

JCO7 Rec'd PCT/PTO 21 MAR 2001

FORM PTO-1390  
REV. 5-93

US DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTORNEYS DOCKET NUMBER  
**P01,0065**

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

**09/787735**

INTERNATIONAL APPLICATION NO.  
**PCT/SE99/01642**

INTERNATIONAL FILING DATE  
**20 September 1999**

PRIORITY DATE CLAIMED  
**21 September 1998**

TITLE OF INVENTION

**MEDICAL IMPLANT**

APPLICANT(S) FOR DO/EO/US

**JOHAN LIDMAN, LARS LANDELIUS and CHARLOTTE KJELLMAN**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
  2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
  3.  This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
  4.  A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
  
  5.  A copy of International Application as filed (35 U.S.C. 371(c)(2)) - drawings attached.
    - a.  is transmitted herewith (required only if not transmitted by the International Bureau).
    - b.  has been transmitted by the International Bureau.
    - c.  is not required, as the application was filed in the United States Receiving Office (RO/US)
  6.  A translation of the International Application into English (35 U.S.C. 371(c)(2)) - drawings attached.
  7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
    - a.  are transmitted herewith (required only if not transmitted by the International Bureau).
    - b.  have been transmitted by the International Bureau.
    - c.  have not been made; however, the time limit for making such amendments has NOT expired.
    - d.  have not been made and will not be made.
  8.  A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
  9.  An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Un-signed
  10.  A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 11. to 16. below concern other document(s) or information included:
11.  An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; (PTO 1449, Prior Art, Search Report).
  12.  An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
  13.  A **FIRST** preliminary amendment.  
 A **SECOND** or **SUBSEQUENT** preliminary amendment.
  14.  A substitute specification and redlined-version
  15.  A change of power of attorney and/or address letter.
  16.  Other items or information:
    - a.  Submission of Ready to Publish Drawings
    - b.  Request for Approval of Drawing Changes
    - c.  Information Disclosure Statement
    - B.  Express Mail Label EJ 778078585US

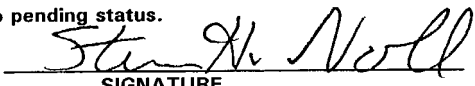
U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5) <b>09/787735</b>	INTERNATIONAL APPLICATION NO. PCT/SE99/01642	ATTORNEY'S DOCKET NUMBER P01,0055
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17. <input checked="" type="checkbox"/> The following fees are submitted:  <b>BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5):</b> Search Report has been prepared by the EPO or JPO ..... \$860.00  International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) \$690.00  No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2)) ..... \$760.00  Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO ..... \$1000.00  International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) ..... \$100.00  <p style="text-align: center;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></p>				CALCULATIONS	PTO USE ONLY	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 1000.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).				\$		
Claims	Number Filed	Number Extra	Rate			
Total Claims	13 - 20 =	0	X \$18.00			
Independent Claims	1 - 3 =		X \$ 80.00	\$		
Multiple Dependent Claims			\$270.00 +			
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$1000.00		
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)				\$		
<b>SUBTOTAL =</b>				\$1000.00		
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$		
<b>TOTAL NATIONAL FEE =</b>				\$1000.00		
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property				+		
<b>TOTAL FEES ENCLOSED =</b>				\$1000.00		
				Amount to be refunded	\$	
				charged	\$	

- a.  A check in the amount of \$1000.00 to cover the above fees is enclosed.
- b.  Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 501519. A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

  
 SIGNATURE

Steven H. Noll  
 NAME

28,982 (Registration No.)

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 Customer No. 26574

09/787735

JC10 Rec'd PCT/PTO 2 1 MAR 2001

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BOX PCT  
IN THE UNITED STATES ELECTED OFFICE  
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UNDER THE PATENT COOPERATION TREATY-CHAPTER II  
5 SUBMISSION OF "READY TO PUBLISH" DRAWINGS

APPLICANT: Johan Lidman et al

DOCKET NO: P01,0065

SERIAL NO:

GROUP ART UNIT:

EXAMINER:

10 INTERNATIONAL APPLICATION NO: PCT/SE99/01642

INTERNATIONAL FILING DATE: 20 September 1999

INVENTION: "MEDICAL IMPLANT"

Assistant Commissioner for Patents  
Washington, D.C. 20231

15 Sir:

Applicants herewith submit seven sheets (Figs. 1-8)  
of "ready to publish" drawings for the above-referenced  
PCT application.

Respectfully submitted,

20

  
(Reg.No. 28,892)

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CUSTOMER NO. 26574

09/787735

BOX PCT

IN THE UNITED STATES ELECTED OFFICE  
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UNDER THE PATENT COOPERATION TREATY-CHAPTER II

5

REQUEST FOR APPROVAL OF DRAWING CHANGES

APPLICANT: Johan Lidman et al

DOCKET NO: P01,0065

SERIAL NO:

GROUP ART UNIT:

EXAMINER:

10

INTERNATIONAL APPLICATION NO: PCT/SE99/01642

INTERNATIONAL FILING DATE: 20 September 1999

INVENTION: "MEDICAL IMPLANT"

Assistant Commissioner for Patents

Washington, D.C. 20231

15

Sir:

Applicants herewith request approval of the drawing changes in each of Figs. 1, 3, 4, 5, 6 and 8, as shown on the drawing copies attached hereto marked in red.

Respectfully submitted,

20

  
Reg.No. 28,892)

Steven H. Noll

**SCHIFF HARDIN & WAITE**

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6600 Sears Tower

Chicago, Illinois 60606

(312) 258-5790

Attorneys for Applicants

**CUSTOMER NO. 26574**

25

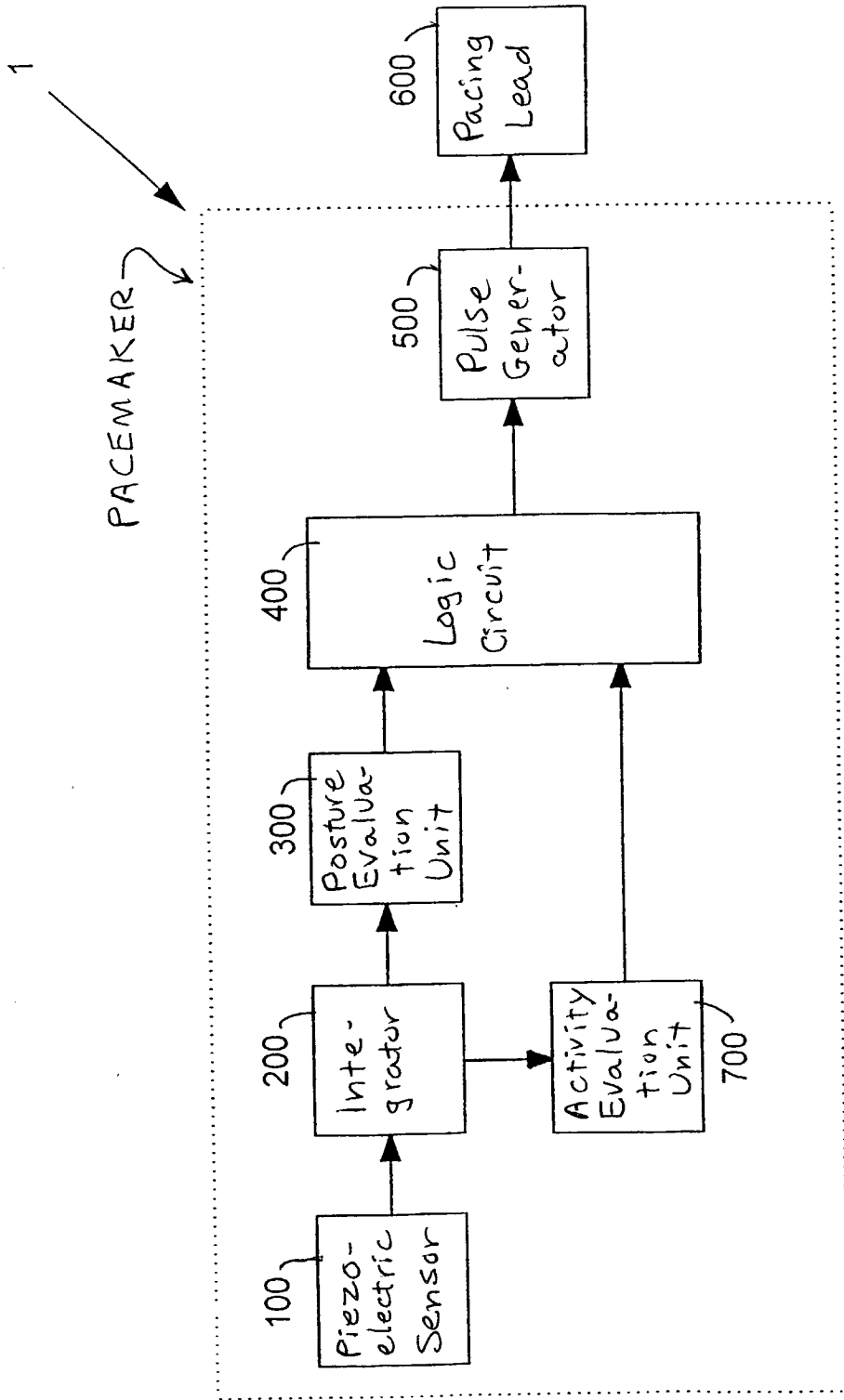


Figure 1

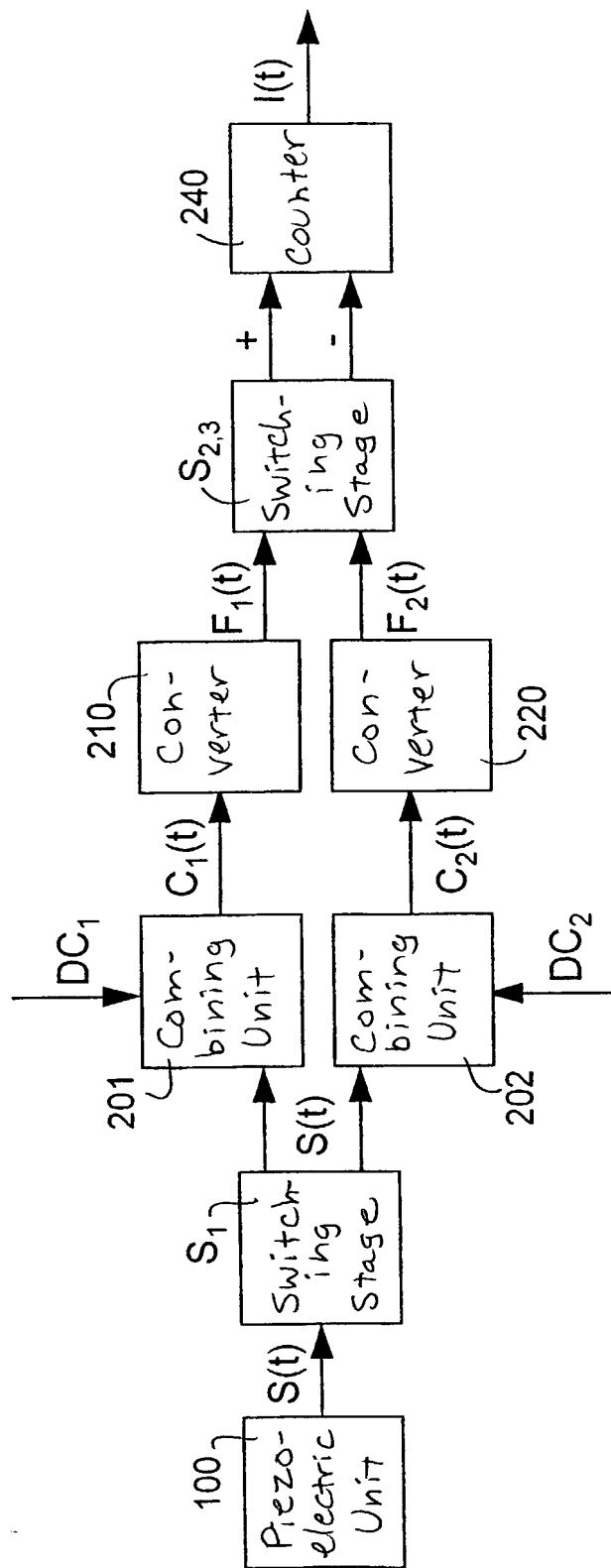


Fig. 3

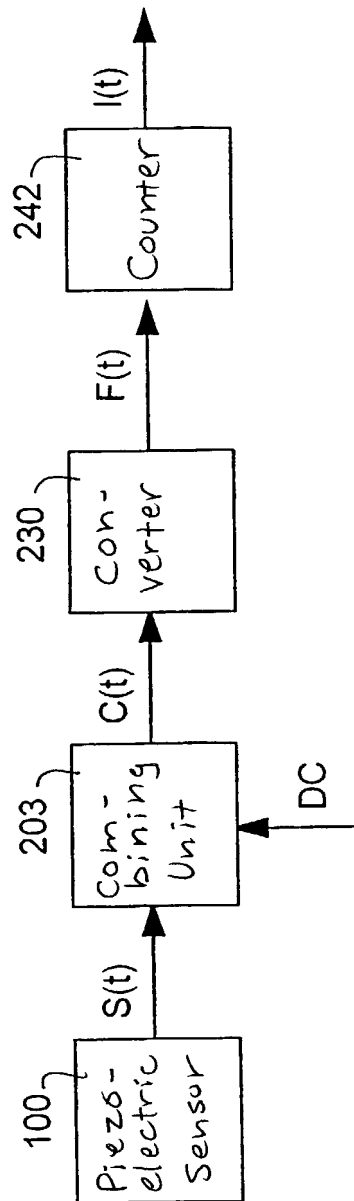


Fig. 5

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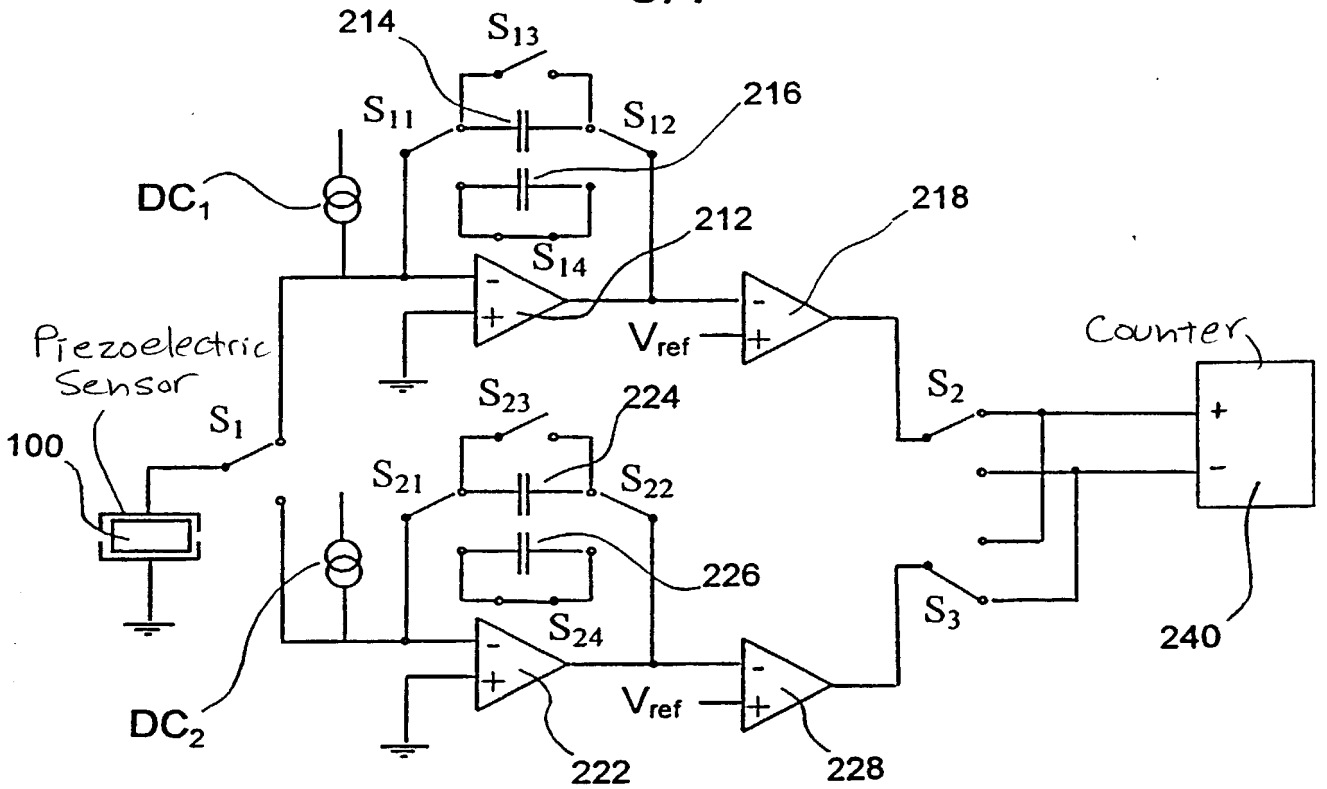


Fig. 4

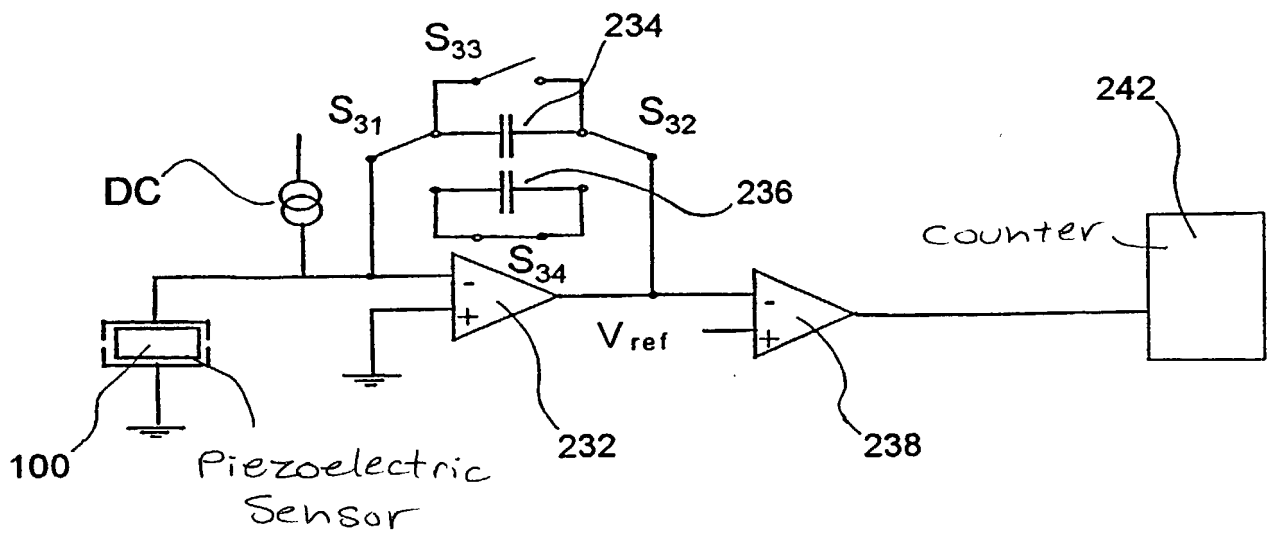


Fig. 6



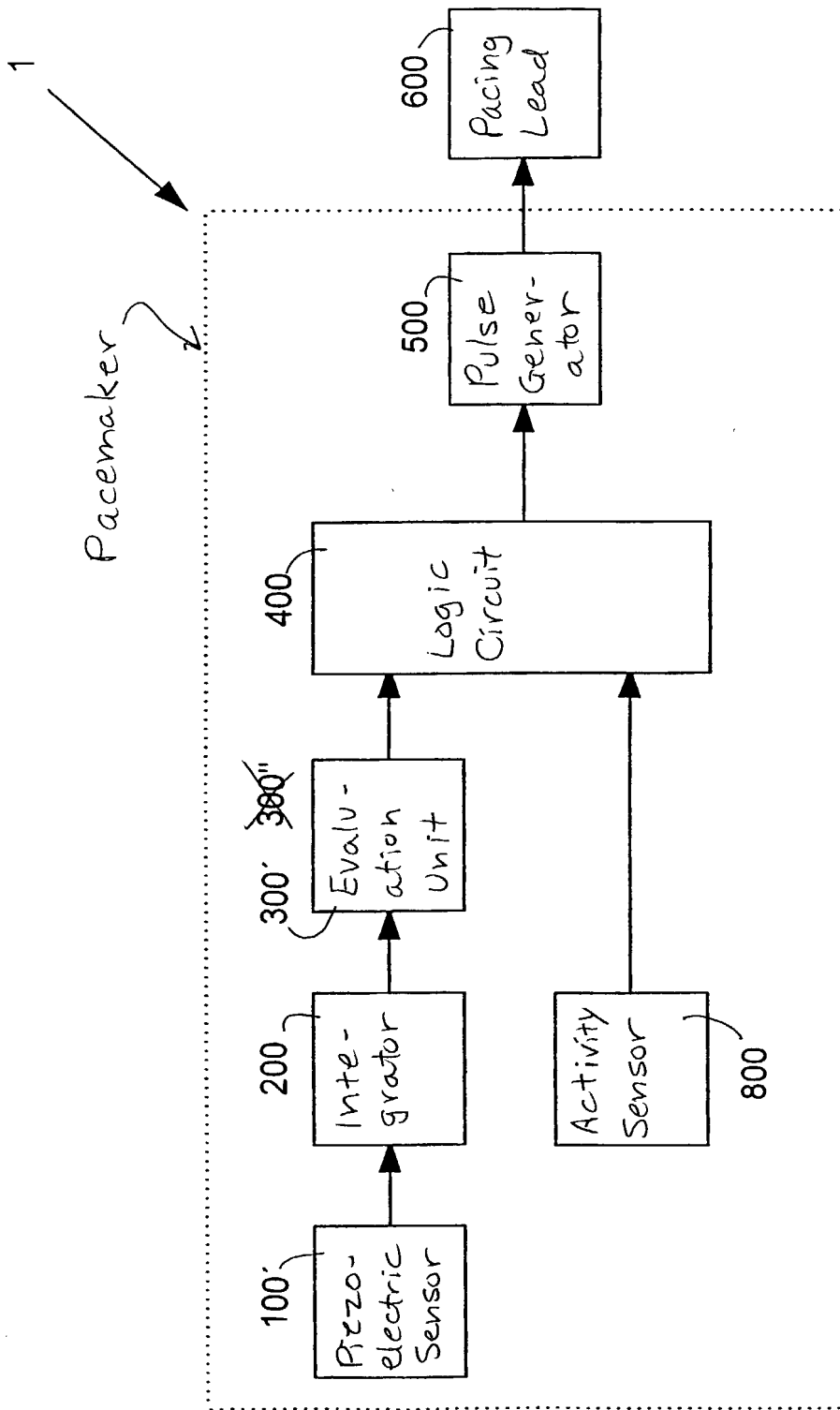


Fig. 8

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BOX PCT  
IN THE UNITED STATES ELECTED OFFICE  
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UNDER THE PATENT COOPERATION TREATY-CHAPTER II  
5 **AMENDMENT "A" PRIOR TO ACTION AND**  
**SUBMISSION OF SUBSTITUTE SPECIFICATION**

APPLICANT: Johan Lidman et al

DOCKET NO: P01,0065

SERIAL NO:

GROUP ART UNIT:

10

EXAMINER:

INTERNATIONAL APPLICATION NO: PCT/SE99/01642

INTERNATIONAL FILING DATE: 20 September 1999

INVENTION: **"MEDICAL IMPLANT"**

Assistant Commissioner for Patents,

15

Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT  
application, and request entry of the Amendment prior to  
examination on the merits in the United States national  
20 examination phase.

**IN THE TITLE:**

Please cancel the present title and substitute the  
following title therefor: --APPARATUS FOR DETERMINING THE  
ACTUAL STATUS OF A PIEZOELECTRIC SENSOR IN A MEDICAL  
25 IMPLANT--.

**IN THE SPECIFICATION:**



5 sensor, for maintaining an accumulated charge potential of said sensor at a substantially zero level, and for generating a sensor output current from said detected positive and negative charges;

10 an integrator supplied with said sensor output current which integrates said sensor output current to produce an integrated signal representing a status of said sensor; and

15 said integrator including a current-to-frequency converter which converts said sensor output current into a frequency signal having a frequency representing a level of said sensor output current, and a counter supplied with said frequency signal for subjecting said frequency signal to a counting operation to obtain said

20 integrated signal.

15. An apparatus as claimed in claim 14 wherein said sensor is a piezoelectric sensor.

16. An apparatus as claimed in claim 14 wherein said integrator further includes:

25 a combining unit for combining said sensor output signal with a DC signal, to obtain a combined signal having an offset DC level, said DC signal being such that a change of sign of said sensor output current does

not result in any change of sign of said combined signal, said combined signal being supplied to said current-to-frequency converter, and causing an output from said counter to contain an integration contribution from said DC signal; and  
5 a unit supplied with said output from said counter for removing said integration contribution from said DC signal to produce said integrated signal.  
10

17. An apparatus as claimed in claim 16 wherein said unit for removing said integrated contribution from said DC signal comprises:  
15 a first switching stage for repeatedly switching said sensor output current between two parallel signal processing paths;  
in each of said two parallel signal processing paths, a unit for generating a processing path output signal which comprises an information output signal dependent on  
20 said combined signal when the signal processing path containing the unit is receiving the sensor output current and which comprises an idle output signal dependent on said DC signal when the  
25 signal processing path containing the unit is not receiving the sensor output current; and

a unit which combines the respective output signals from said two parallel signal processing paths.

18. An apparatus as claimed in claim 17 wherein  
5 each of said two parallel signal processing paths comprises:

a signal path combiner for combining the sensor output current, when said sensor output current is received in the signal processing path, with said DC signal to  
10 obtain a signal path combined signal having said DC offset level; and

a converter for combining the signal path combined signal into a frequency signal having a frequency corresponding to a level of the frequency path combined signal, so that  
15 said output signal has a non-zero frequency; and

wherein said unit for combining said output signals from  
20 the two parallel signal processing paths is a counter.

19. An apparatus as claimed in claim 16 wherein said integrator further includes:

a first capacitor and a second capacitor;  
circuitry supplied with said combined signal for  
25 alternately charging and discharging said first and second capacitors dependent on said combined signal so that when one of said first and second capacitors as being charged by said combined signal the



22. An apparatus as claimed in claim 21 wherein said filter subjects said integrated signal to low-pass filtering to obtain a low-pass filtered signal, and wherein said evaluating unit includes a unit for  
5 evaluating said low-pass filtered signal to generate a value representing an orientation of said medical implant.

23. An apparatus as claimed in claim 22 wherein said unit for evaluating said low-pass filtered signal  
10 compares said low-pass filtered signal to respective, predetermined threshold values, said threshold values respectively corresponding to predetermined orientations of said medical implant, to obtain a comparison result as said value representing an orientation of the medical  
15 implant.

24. An apparatus as claimed in claim 21 further comprising an additional evaluating unit containing a bandpass filter for bandpass filtering said integrated  
20 signal to obtain a bandpass filtered signal, and a unit for evaluating said bandpass filtered signal to obtain a value representing a physical activity level of a person in whom said medical implant is implanted.

25. An apparatus as claimed in claim 14 wherein said sensor is sensitive to positive and negative changes  
25 in said load in only one direction.

26. An apparatus as claimed in claim 14 wherein said sensor is a piezoelectric sensor, and further



comprising an activity sensing unit supplied with said  
sensor signal which identifies whether said changes in  
said load on said piezoelectric sensor result from  
physical activity of a patient in whom said medical  
5 implant is implanted.

**IN THE ABSTRACT:**

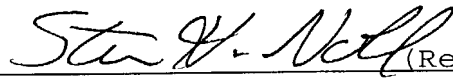
Please add the Abstract shown on separately  
numbered page 32 attached hereto.

**REMARKS**

10 The present amendment revises the title,  
specification, drawings and claims, and adds an Abstract,  
to conform the above-referenced PCT application to the  
requirements of United States patent practice. The  
cancellation of claims 1-13 in favor of claims 14-26  
15 presented herein has been made solely because the amount  
of bracketing and underlining in the original claims  
which would have been necessary to conform those claims  
to the requirements of 35 U.S.C. §112, second paragraph  
would have been unduly burdensome and confusing. No  
20 difference in the claim language between the claims  
presented herein and the original claims has been made  
for the purpose of distinguishing any of the claims  
presented herein over the teachings of the prior art of  
record. Accordingly, no change in the claim language  
25 between the original claims and the claims presented  
herein is intended by the Applicants as a surrender of  
any of the subject matter encompassed within the scope  
of original claims 1-13.

Early consideration of the application on the merits is respectfully requested.

Respectfully submitted,



(Reg.No. 28,892)

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**CUSTOMER NUMBER 26574**

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10

**ABSTRACT OF THE DISCLOSURE**

In an apparatus for determining the actual status of a piezoelectric sensor in a medical implant, electrical charges generated in the sensor, in response to changes in acceleration and/or gravitational force or other loads acting on the sensor, are continuously detected and the charges are then removed from the sensor, thereby maintaining the voltage across the sensor at a substantial constant zero level. The detected charges, both negative and positive, are integrated, thereby providing a resulting integrated signal representing the actual status of the sensor. The integrated signal is then evaluated for determining the physical activity and/or the posture of a patient in whom the medical implant is implanted.



an attempt to solve this problem, use has been made of a voltage amplifier having a very high input impedance. This requires, however, a very large resistance component, which is undesired within a medical implant. Furthermore, the problem related to leaking charges is still not completely eliminated, and the use of a memory function of some sort would be required. The problem of leaking charges is of particular interest when the piezoelectric sensor is subjected to relatively small changes in load over long time periods, such as small changes of pressure over a long time or changes in posture.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a method and apparatus for determining the status of a piezoelectric sensor that takes the leakage of charges mentioned above into account.

A further object of the present invention is to improve the possibilities of evaluating the status of a piezoelectric sensor.

These objects are achieved in accordance with the present invention wherein status related sensor output changes are substantially continuously detected, and based thereupon a signal representing the actual status of a sensor is generated. Advantageously, said signal is generated by integration of the sensor output changes.

Preferably, use is made of a sensor of the type in which status changes generate changes regarding electrical charges in the sensor. Thus, the sensor is suitably of the piezoelectric type.

In accordance with a preferred aspect of the invention, positive and negative charges generated by the sensor, as more closely discussed below, are substantially continuously detected and removed from the sensor, thereby keeping the output voltage of the sensor at a substantially constant zero level, while at the same time providing an output current which can be the basis for an integration in order to produce the signal.

According to an embodiment of the invention, this can be accomplished by connecting the charge-producing sensor to a circuit having the characteristics of an input impedance that is extremely low or redundant. As a result, charges generated by the piezoelectric sensor will immediately leak to, or be collected or removed by, the

connected circuit. This also means that there will be no problem with uncontrolled leakage of charges from the sensor, as is the case in the prior art.

As indicated above, a change of load generates a change of charges in a sensor of the piezoelectric type, all charges generated being collected, i.e. detected and removed from the piezoelectric sensor, by the connected circuit. A change of load can be either  
5 positive or negative. A positive change of load will generate an internal transport of charges in a direction opposite that caused by a negative change of load. Furthermore, if a transport of charges in one direction generates a positive voltage across the piezoelectric sensor, a transport of charges in the opposite direction generates a negative voltage. Hence, for restoring a zero voltage level across the sensor from a positive voltage level,  
10 there must be a transport of "actual" charges from the sensor, while for restoring a zero level from a negative voltage, there must be a transport of "actual" charges from the connected circuit to the sensor.

In accordance with the above, the actual charges supplied to the sensor for restoring a zero level will hereinafter be referred to as collected or removed negative  
15 charges, and the resulting current will be referred to as a negative current. Correspondingly, the actual charges removed from the sensor will be referred to as positive charges, and the resulting current as a positive current. Therefore, both the supply and the removal of charges to and from the sensor hereinafter will be referred to as a collection of charges, wherein a supply of charges to the sensor will be referred to as a  
20 collection of negative charges, and a removal of charges from the sensor will be referred to as a collection of positive charges.

The charges generated in a sensor of the type discussed correspond to the load (e.g. acceleration and/or gravitational force or pressure) to which the sensor is subjected. Accordingly, each generated charge represents a certain change of load. A greater change  
25 of load generates more charges; a more rapid change of load provides a more rapid generation of charges; and an change of load in one direction generates positive charges and an change of load in the opposite direction generates negative charges (in accordance with the above stated definition of positive and negative charges). Hence, the electric charges generated by the sensor per time unit, i.e. electric current, correspond to the

amount and the direction of the change of load and, hence, to the time derivative of the load to which the sensor is subjected.

The charges generated by a piezoelectric sensor, as described above, are provided to a circuit for detecting and removing these charges. Since the number of generated charges per time unit, hereinafter referred to as the sensor current or sensor output current, is proportional to the time derivative of the change of load, an integration of said current will result in an integrated value or signal that is proportional to the load.

The circuit for receiving the current (detecting and removing the charges) is, according to the invention, arranged to integrate said current, i.e. to quantify and to cumulate the charges generated by the sensor. Accordingly, the resulting value from this integration will represent the net amount, i.e. considering the sign of the generated charges, of charges generated by the sensor. Thus, the integrated value, or signal, will be directly representative of the load to which the sensor currently is subjected. The integrated value can therefore be seen as a re-creation of the voltage that would have existed in the sensor, provided that there would have been no leakage or deliberate removal of charges at all. Thus, the present invention solves the problem regarding obtaining an absolute value representative of the level of for instance a constant acceleration or gravitational force or pressure by the use of a piezoelectric type sensor.

As stated above, the restoring in the sensor of a zero level from a negative voltage level would require a supply of charges from the connected circuit to the sensor.

According to an embodiment of the invention, the supply of charges can be provided by connecting a constant direct current, hereinafter referred to as a DC signal, to the sensor and the circuit. If the magnitude of the DC signal exceeds the possible maximum magnitude of the positive and the negative sensor current, the charges or the current supplied to the sensor for restoring the zero level will be provided by the added DC signal. As a result, the connected circuit will be provided with a combined signal, this combined signal being the sum of the DC signal and the sensor current. The combined signal will, e.g., have the magnitude of the DC signal when the sensor is not affected by a change in acceleration and/or gravitational force or pressure; a magnitude greater than the DC signal when the sensor is affected by a positive change in load, for instance

acceleration and/or gravitational force; and a magnitude less than the DC signal when the sensor is affected by a negative change in said load.

As described above, the connected circuit integrates the sensor current. According to preferred embodiments of the invention, this integration can be accomplished by first subjecting the sensor current to a current to frequency conversion. The provision of an added DC signal to provide a combined signal, as described above, is particularly advantageous when used in conjunction with a current to frequency converter, in that the combined signal will always be kept positive and the frequency can be kept proportional to the level of the combined signal.

The current to frequency conversion produces a frequency signal that will be provided to a counted means for counting the pulses comprised in the frequency signal. The counting operation will generate the desired integrated value, after compensation for the contribution from the added DC signal, that will be directly representative of the actual acceleration or gravitational force by which the sensor is affected.

The contribution of the added DC signal, however, must be eliminated in order to obtain an integrated signal representing the immediate influence of the load on the sensor. According to an embodiment of the invention, the contribution of the added DC signal can be removed by deducting in the counter a counter value corresponding to the contribution from the DC signal. After each deduction, the counter value, i.e. the integrated value, will represent the contribution from the sensor current only, and, hence, from the load to which the sensor is affected.

The value to be deducted, herein referred to as a deduction value, can be obtained by disconnecting the sensor from the connected circuit for a given time period, and by registering the pulses in the frequency signal during said time period. Disconnection of the sensor can simply be provided by a switch. When this time period expires, the number of pulses registered during this time period is stored as the deduction value and the operation of the connected circuitry continues, using the updated deduction value, as described above. The operation for obtaining the deduction value can be performed at given time intervals, but is preferably performed when there is no sensor current.



In another embodiment of the present invention, the problem in compensating for the contribution of the added DC signal can be solved by providing two parallel signal paths, each path being provided with a separate DC signal, as described above, and including a current to frequency converter, a first switch for switching the sensor current between the two signal paths, a second switch for switching the respective frequency signal from the respective signal path between incrementing and decrementing inputs of an up-down counter, and an up-down counter.

The sensor current is periodically switched between the respective paths, so that the sensor current is half the time provided to the one path, half the time to the other path. As a result, the converted frequency signal output by each path will half the time comprise the converted combined signal, half the time a frequency conversion of the added DC signal. The converted signal, when including the contribution of the DC signal only, can be seen as an idle frequency signal. Obviously, when the sensor current is zero, a frequency conversion of the combined signal will have the same frequency as the idle frequency signal, regardless of the state of the first switch means.

The frequency signal output by each signal path is periodically switched between incrementation and decrementation inputs of an up-down counter. This switching is preferably performed in conjunction with the switching of the sensor current between the respective signal paths, so that the path presently receiving the sensor current is connected to the incrementing input of the up-down counter, and that the path presently not receiving the sensor current is connected to the decrementing input of the up-down counter. Hence, the respective frequency signal will increment the counter when including the contribution of the sensor current, and decrement the counter when not including the contribution of the sensor current. Accordingly, the contribution of the respective added DC signals will be completely eliminated and the integrated value output by the up—down counter will be directly representative of the current generated by the sensor. The contribution of the respective added DC signal will be completely eliminated, regardless of any drift of the DC signal over time and regardless of the difference between the DC signals.

According to this embodiment, the counter value, i.e. the integrated value, is constantly being updated and at all times represents the load to which the sensor presently is subjected.

One way of determining the activity level of a patient is to use a piezoelectric accelerometer in a medical implant to determine the physical activity of the patient and consequently the rate at which the heart of the patient is to be stimulated.

However, the heart rate in a healthy individual is also dependent of the individual's static or long term physical body orientation or posture, or a change from one such orientation to another, e.g. from standing to lying down. The intrinsic heart rate is even dependent of whether the individual is lying in a supine, i.e. on his/her back, or in a prone position, i.e. on his/her face. Therefore, there is a need for establishing both the activity level and the body posture of a pacemaker patient, in order to control the operation of the pacemaker in dependence of the activity level and the posture of the patient.

A number of different methods and devices have been proposed for determining the physical orientation or posture of a patient. Generally, accelerometers are used for determining posture, as described for instance in European Application 0, 845,240. This is due to the fact that gravitational force affects an object in the same manner as would a corresponding constant acceleration force. By determining the effect of gravitation on an accelerometer that is sensitive to acceleration forces in a certain direction only, the gravitation component in this direction can be measured and, hence, the angle between the axis of sensitivity and the direction of the gravitational force can be determined. Knowing the orientation of the accelerometer relative the patient, the posture of the patient then can be easily established.

The accelerometer also can be combined with one or more accelerometers having different directions of sensitivity, preferably perpendicular to that of the first accelerometer. Thereby, the possibility of detecting different postures of the patient will increase. For instance, the combination with an accelerometer having a sensitivity in the right-left direction of the patient, would enable distinguishing an upright position from a position where the patient is lying on his/her side.

Since the changes in acceleration and gravity connected with changes in posture are relatively slow compared to the changes in acceleration connected with normal physical activity and the device according to the invention takes the leakage of charges from the piezoelectric accelerometer into account, the invention is of particular interest in piezoelectric devices for detecting changes in posture.

5 As discussed above, the constantly updated integrated value represents the acceleration and/or gravitational force (i.e. the component of the gravitational force in the direction of sensitivity of the accelerometer) to which the accelerometer presently is subjected. The maximum contribution the accelerometer can be subjected to by the gravitational force corresponds to an acceleration of 1 g (9.81 m/s<sup>2</sup>). However,  
10 accelerations associated with heavy exercise, such as running, can significantly exceed 1 g, sometimes even exceed 2 g. Therefore, the integrated value will suitably be subjected to further processing in order, e.g., to distinguish between contribution from gravitation and contribution from physical activity.

15 According to an embodiment of the invention, the constantly updated integrated value can be provided as a digital output signal from the described counter to a posture evaluation unit for determining the posture of the patient. This posture evaluation unit, or circuitry connected between the posture evaluation unit and the counter, performs a digital low pass filtering of the integrated signal. This low pass filtering, preferably having a cut-off frequency of less than about 1 Hz, preferably about 0,5 Hz, will effectively filter out  
20 the contributions of activity, heart beats etc. The low pass filtered integrated signal then can be compared to threshold values for obtaining a posture value indicating the actual posture of the patient. This posture value can then be provided to a control unit for controlling the operation of a pacemaker in accordance with the posture of the patient, in a known manner.

25 Likewise, according to a further embodiment of the invention, the integrated value also can be provided as a digital output signal to an activity evaluation unit for determining the physical activity of the patient. This activity evaluation unit, or circuitry connected between the activity evaluation unit and the counter, performs a digital band pass filtering of the integrated signal. This band pass filtering preferably has a lower cut-

off frequency of about 1 Hz, and has a preferred upper cut-off frequency of about 10 Hz, preferably about 6 Hz. The band pass filtered integrated signal can then be evaluated in a known manner for obtaining an activity value indicating the physical activity of the patient. This activity value can then be provided to a control unit for controlling the operation of a pacemaker in accordance with the physical activity and the posture of the patient.

In another embodiment of the invention, use is made of a piezoelectric accelerometer formed by a two layer beam, one piezoelectric layer and one supporting layer, this beam being fixed to a mounting surface at one end and provided with a weight at the other end. Thus, when affected by an acceleration or gravitational force change, the beam will deflect around the fixed end. The beam is preferably wide, which would prevent the beam from twisting or deflecting in other directions than intended. The beam also can be tilted. This tilt and the width of the beam will produce sensitivity to acceleration and gravitation changes in a direction perpendicular to the mounting surface only. Thus, the piezoelectric accelerometer can be said to be of a monoaxial type. The width of the beam also enhances the magnitude of the current generated by the piezoelectric layer. When the accelerometer is subjected to acceleration and/or gravitational forces directed perpendicular to the mounting surface, the beam will deflect around the fixed end, and the piezoelectric material will generate charges in dependence of the rate and magnitude of the acceleration and/or gravitational changes.

Furthermore, according to this embodiment of the invention, the piezoelectric accelerometer is positioned in such a way within a pacemaker that, when the pacemaker is implanted in a patient, the accelerometer beam is positioned vertically with its direction of sensitivity being the anterior-posterior direction of the patient, with the advantages described above. Since the piezoelectric accelerometer is capable of providing negative values, the prone position can easily be distinguished from the supine position.

As indicated above, the invention also is applicable to other piezoelectric sensors, such as endocardial pressure sensors for measuring the intracardiac pressure.

It is for instance possible to determine changes in posture by means of an intracardiac pressure sensor. The hydrostatic pressure acting on the sensor increases when

the patient rises from a prone or supine position to an upright position since the vertical distance upwardly from the sensor within the patient that defines the hydrostatic pressure will increase. The effects of an increase in pressure on the pressure sensor will generally be similar to the effects of acceleration or gravity on an accelerometer of the type described above. The arrangement described above used for evaluating the accelerometer signal thus could be used also for evaluating the signal from the pressure sensor. Since a pacer system normally contains some kind of activity sensor, the pressure signal also additionally could be evaluated by means of the signal from the activity sensor in order to better distinguish the rise in pressure resulting from a change in posture from a change in pressure resulting from a change in activity.

A further use of the arrangement according to the invention is to detect long-term changes or drift in the intracardial pressure by means of a pressure sensor.

#### DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of a medical implant having an apparatus according to the present invention.

Figure 2 illustrates a piezoelectric accelerometer according to a preferred embodiment of the present invention.

Figure 3 is a block diagram and Figure 4 is a circuit diagram of an apparatus according to a first embodiment of the invention.

Figure 5 is a block diagram and Figure 6 is a circuit diagram of an apparatus according to a second embodiment of the invention.

Figure 7 is a pulse diagram illustrating the method according to the present invention.

Figure 8 is a block diagram of an apparatus according to a third embodiment of the invention.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

As mentioned above, the invention is applicable to accelerometers and in particular to accelerometers used in connection with pacemakers and similar for detecting changes in posture, and the invention will be described in more detail below with reference to such an accelerometer. Referring to Figure 1 there is shown a schematic

block diagram of a pacemaker 1 according to the invention. The pacemaker 1 according to the invention includes a piezoelectric sensor (accelerometer) 100, an integrator 200, a posture evaluation unit 300, a logic circuit 400, and a pulse generator 500. The logic circuit 400 is also connected to an activity evaluation unit 700, provided with an activity signal originating from the piezoelectric accelerometer 100. The pacemaker 1 is further connected to at least one pacing lead 600 provided with at least one stimulating electrode, this electrode also being used for sensing. The pacemaker 1 further includes processing circuitry for processing the sensing signal(s) from this electrode(s) (not shown). The pacemaker 1 may be arranged for unipolar or bipolar stimulation as is well known to those skilled in the art.

The piezoelectric accelerometer 100 will now be described with reference to Figure 2. The pacemaker 1 of Figure 1 has a piezoelectric monoaxial accelerometer 100, formed by a two layer beam that is at one end fixed via a support 110 to a surface 120, the beam being tilted with respect to the mounting surface 120. The other end, the free end, is provided with a weight (mass) 108 that produces a bending or deflecting motion around the fixed end. The upper layer 102 of the beam is made of a piezoelectric ceramic material, the lower supporting layer 104 is formed of a high density, high Young's module material. The support 110, the weight 108 and the supporting layer 104 are all made in one piece, the piece being electrically conductive. The layers 102, 104 are adhesively fixed to each other using an electrically conductive adhesive 106. The free upper side of the piezoelectric layer is coated with a thin metallic layer serving as an electrode. The piezoelectric layer 102 is connected to surrounding circuitry via the conductive layer 104 and a lead 112, connected to the metallic layer.

Figures 3 and 5 show the sensor 100 and the integrator 200 according to preferred embodiments of the present invention. The integrator 200 has combining units 201, 202, 203 for combining a sensor output current  $S(t)$  with a DC signal, thereby obtaining a combined signal  $C(t)$  with an offset DC level; converters 210, 220, 230 for converting the combined signal  $C(t)$  into a frequency signal  $F(t)$ ; and counters 240, 242 for subjecting the frequency signal  $F(t)$  to a counting operation for obtaining an integrated signal  $I(t)$ .

Referring specifically to Figure 3, according to a specific preferred first embodiment of the invention, the integrator 200 further includes a first switch  $S_1$ , for repeatedly switching the sensor output current  $S(t)$  between two parallel signal processing paths, respectively having combining units 201, 202, for combining the sensor output current  $S(t)$  with respective DC signals  $DC_1$ ,  $DC_2$ , thereby obtaining respective combined signals  $C_1(t)$ ,  $C_2(t)$ , and converters 210, 220, for converting the respective combined signals  $C_1(t)$ ,  $C_2(t)$  to respective frequency signals  $F_1(t)$ ,  $F_2(t)$ . The integrator 200 further has a second switch  $S_{2,3}$  for switching the frequency signals  $F_1(t)$ ,  $F_2(t)$  between inputs of a counter 240. The counter 240 combines the output signals  $F_1(t)$ ,  $F_2(t)$  from the two separate signal processing paths, thereby obtaining the integrated signal  $I(t)$ .

The apparatus according to the specific first embodiment of the present invention will now be described in greater detail with particular reference to Figures 3 and 4. The pacemaker 1 of Figure 1 has a piezoelectric accelerometer 100, as described above. The integrator 200 of Figure 1 according to this first embodiment has a first switch  $S_1$  for switching the output signal  $S(t)$  from the piezoelectric accelerometer 100 between two parallel, substantially similar signal paths. The switch  $S_1$  is controlled by a constant, periodic control signal that ensures that the output signal  $S(t)$  from the sensor is provided equal time to the respective signal paths. The switching frequency is typically set from about 100 to about 1000 Hz.

The integrator 200, in each of the signal paths, also includes counters 201, 202, for combining the output current  $S(t)$  from the piezoelectric accelerometer 100 with a DC signal originating from current sources  $DC_1$ ,  $DC_2$ , thereby providing combined signals  $C_1(t)$ ,  $C_2(t)$ . The magnitude of the added DC signals  $DC_1$ ,  $DC_2$  is greater than the expected maximum value of the accelerometer current from the piezoelectric accelerometer 100.

When the switch  $S_1$  is in a position for switching the sensor output current  $S(t)$  to one signal path, the output from the combining units 201, 202 in the respective other signal paths includes only the respective added DC signal.

Furthermore, each signal path of the integrator 200 includes a converter 210, 220, in the form of an amplifier circuit functioning as a current to frequency converter, for converting the respective combined signals  $C_1(t)$ ,  $C_2(t)$  into respective frequency signals

$F_1(t)$ ,  $F_2(t)$ . The amplifier circuits respectively include first operational amplifiers (op amp) 212, 222; first and second capacitors 214, 216, 224, 226, four switches  $S_{11}$ - $S_{14}$ ,  $S_{21}$ - $S_{24}$ ; and comparators 218, 228. The respective combined signals  $C_1(t)$ ,  $C_2(t)$ , with or without the contribution of the sensor output current  $5(t)$ , are provided to the first operational amplifiers 212, 222.

5           When the switches  $S_{11}$ - $S_{14}$ ,  $S_{21}$ - $S_{24}$  are in the states shown in Figure 4, the first operational amplifiers 212, 222 are respectively fed back by the first capacitors 214, 224 and charge the respective capacitors 214, 224. The comparators 218, 228, each shown as a second operational amplifier, respectively compare the charge of the first capacitors 214, 224 to a reference voltage  $V_{ref}$ .

10           When the charge of either of the first capacitors 214, 224 exceeds the reference voltage, the respectively connected comparators 218, 228 provides an output signal that produces switching of the switches  $S_{11}$ - $S_{14}$  or  $S_{21}$ - $S_{24}$  to their second state, thereby discharging the first capacitor 214 or 224 and charging of the second capacitor 216 or 226 commences. When the input signal to either comparator 218, 228 once again exceeds  
15 the reference voltage  $V_{ref}$ , the switches  $S_{11}$ - $S_{14}$  or  $S_{21}$ - $S_{24}$  switch back again and the procedure is repeated. The respective output signals of the comparators 218, 228 represent the frequency with which the first and second capacitors 214, 216, 224, 226 are discharged. Thus, the respective outputs from the comparators 218, 228 provide  
20 respective frequency signals  $F_1(t)$ ,  $F_2(t)$ .

25           The rate at which the capacitors are discharged obviously depends of the current level of the combined input signal  $C_1(t)$  or  $C_2(t)$ . However, the level of the combined signal  $C_1(t)$  or  $C_2(t)$  is selected so that the frequency of the output frequency signal  $F_1(t)$  or  $F_2(t)$ , converted from the combined signal  $C_1(t)$  or  $C_2(t)$ , always exceeds the switching frequency for switching the switch  $S_1$ . Actually, half the time, the combined signal will be composed solely of the DC signal  $DC_1$  or  $DC_2$ . When the signal path receives the combined signal  $C_1(t)$  or  $C_2(t)$  solely containing the DC signal contribution, the output from the comparator 218 or 228 constitutes an idle frequency signal  $F_{01}$  or  $F_{02}$ . The frequency of said idle frequency signal  $F_{01}$  or  $F_{02}$  will be in the magnitude of 10-100 kHz, i.e. by far exceeding the switching frequency for switching the switch  $S_1$ .



The integrator 200 further has a switching stage  $S_{2,3}$  in the form of a first switch  $S_2$  and a second switch  $S_3$ , for respectively switching the output frequency signals  $F_1(t)$ ,  $F_2(t)$  from the respective signal paths between the respective positive and negative inputs of a counter 240. The first and second switches  $S_2$ ,  $S_3$  operate in an opposed manner so that when the first switch  $S_2$  connects one signal path to the positive input of the counter 240, the second switch  $S_3$  connects the other signal path to the negative input of the counter 240. The switches 32, 33 are controlled by the same constant, periodic control signal noted above with respect to controlling the switch  $S_1$ , this switching frequency being 20 Hz. Thus, the respective signal paths are connected to one input of the counter 240, i.e. the positive input, when the path is currently receiving the sensor output current  $S(t)$ , and, accordingly, are connected to the other input, i.e. the negative input, when the path is not receiving the output signal  $S(t)$  from the piezoelectric accelerometer 100.

The integrator 200 further has a counter 240 in the form of an up-down counter for counting the pulses of the frequency signals  $F_1(t)$ ,  $F_2(t)$  produced by the above described comparators 218 and 228, thereby obtaining the integrated signal  $I(t)$ . The up-down counter 240 includes a positive input for incrementing the counter 240 and a negative input for decrementing the counter 240. Each output pulse included in the frequency signal  $F_1(t)$  or  $F_2(t)$  emitted by the respective comparators 219, 229 produces an incrementation or a decrementation of the counter 240, depending of the state of the switches  $S_2$  and  $S_3$ .

The pacemaker 1 shown in Figure 1 further has a posture evaluation unit 300 for evaluating the integrated signal  $I(t)$  and obtaining a value directly representative of the physical posture of the patient. The digital low pass filtering with a cut-off frequency of 0,5 Hz is performed by the posture evaluation unit 300, or by means not shown connected between the integrator 200 and the evaluation unit 300. The posture evaluation unit 300 further compares, at certain predetermined time intervals, the integrated, digitally low pass filtered signal to predefined threshold values. The evaluation unit 300 provides a signal to the logic circuit 400 indicative of the following physical posture states when the accelerometer 100 is subjected to a gravitational force contribution corresponding to an acceleration of:

1 g, patient lying in a prone position;  
 0 g, patient being in an upright position; and  
 -1 g, patient lying in a supine position.

5 The evaluation unit 300 can also provide a signal indicative of uncertain posture, e.g. when the posture of the patient changes from a supine to standing position.

According to a specific embodiment of the invention, the pacemaker 1 also has an activity evaluation unit 700 for providing a signal to the logic circuit 400 indicative of the current patient activity. In accordance with the posture evaluation unit 300, the integrated signal I(t) is subjected to a digital band pass filtering for removing signal contribution that is not related to patient physical activity. The upper and lower cut-off frequencies of the digital band pass filtering are 1 Hz and 6 Hz, respectively. The digital band pass filtering per se can be performed in a manner well known to those skilled in the art, and will therefore not be described in greater detail. The output signal from the activity evaluation unit 700 is then provided to the logic circuit 400.

15 The pacemaker 1 shown in Figure 1 further has a logic circuit 400 and a pulse generator 500 for controlling, regulating and delivering pacing pulses, via the pacing leads, to the atrium and/or ventricle of the heart. This control is performed at least on the basis of the posture and activity of the patient in a manner known to those skilled in the art. It should be understood that means and circuits required for the conventional operation of a pacemaker according to the state of the art are included in the pacemaker according to the present invention, although not shown or described here in.

20 Figure 7 shows in diagrammatic form how an acceleration contribution, in an idealized form for explanatory reasons, is represented by the integrated signal. The pulse diagram has six different signals (A-F) divided into five time periods by the dotted lines (1-5).

25 A is the idealised contribution of the gravitation component, in the sensitivity direction of the accelerometer, to which the accelerometer is affected. In a true case, this would be superimposed by the activity and noise contributions constantly present.

B is the current generated by a piezoelectric accelerometer that is subjected to the gravitation component according to A, i.e. the sensor output current  $S(t)$ . This current is proportional to the derivative of the acceleration.

C is the control signal controlling the switches  $S_1$ -  $S_3$ , i.e. the switching of the sensor output current  $S(t)$  between the parallel signal paths and the switching to the up-down counter 240.

D are the output signal pulses delivered by the comparator 218 of the upper signal path, and E are the pulses delivered by the comparator 228 of the lower signal path, in the manner described above. The respective pulses control the respective switches  $S_{11}$ - $S_{24}$  and trigger the incrementation and decrementation of the up-down counter 240. The difference in pulse width is only to illustrate the fact that a difference in the magnitude of the respective DC signals  $DC_1$  and  $DC_2$  does not affect the performance of the integrator 200. The contributions of the DC signals  $DC_1$  and  $DC_2$  are completely eliminated.

F is the resulting integrated signal  $I(t)$  registered in the counter 240 and provided to the posture evaluation unit 300.

During the time intervals 1-2, 3-4 and 5-6, the sensor output current  $S(t)$  is switched to the upper signal path, the comparator of which is switched to the positive input of the up-down counter 240. Accordingly, during these time intervals, signal D increments and signal E decrements the up-down counter 240. Consequently, during time periods 2-3 and 4-5, the sensor output current is switched to the lower signal path L, signal E increments the counter and signal D decrements the counter.

As can be seen in Figure 7, the level of the integrated signal  $I(t)$  provided by the counter 240 closely matches the gravitation component to which the piezoelectric accelerometer 100 currently is subjected. Hence, the output of the integrator 200 according to the invention provides a direct absolute value representing the current deflection of the accelerometer beam and, hence, the current gravitation (or acceleration)

Now, with particular reference to figures 5 and 6, an apparatus according to an alternative second embodiment of the invention will be described. According to this alternative second embodiment, the integrator 200 shown in Figure 1 has only one signal path, thereby precluding the need for first and second switching stages for switching the

sensor output current  $S(t)$  between separate signal paths. As noted above, the integrator 200 has a combining unit 203, a converter 230, and a counter 242. The converter 230 is in the form of an amplifier circuit. This amplifier circuit has a first operational amplifier 232, first and second capacitors 234, 236, four switches  $S_{31}$ - $S_{34}$  and a comparator 238. The functions of the combining unit 203, the converter 230, and the components in the converter 230, are similar to the functions of the corresponding components described above with particular reference to the Figures 3 and 4, and therefore need not be described again in detail.

The counter 242, according to this second embodiment, is a counter for counting the pulses of the frequency signal  $F(t)$ , produced by the comparator 238. As described above, the DC signal is superimposed on the sensor output current  $S(t)$ . The contribution from the DC signal is removed by deducting, at predefined time intervals, e.g. every 1-10 ms, a counter value corresponding to the contribution from the DC signal. The integrated signal  $I(t)$  from the counter is updated after each deduction, and the integrated signal  $I(t)$  is representative of the acceleration or gravitation.

The counter value to be deducted, a deduction value, is obtained by disconnecting, at certain given time intervals, e.g. 1 hour, for a given time period, e.g. 1 sec, the piezoelectric accelerometer 100 from the combining unit 203 by the opening of a switch (not shown) positioned between the accelerometer 100 and the combining unit 203. When the time period expires, the number of pulses registered during this time period is stored as the new deduction value, the switch is closed, and the operation of the integrator 200 continues, with the updated deduction value, as described above.

The pacemaker 1, according to this second embodiment of the invention, also has a posture evaluation unit 300, a logic circuit 400, a pulse generator 500, and an activity evaluation unit 700, in the same manner and with the same functions as described above with reference to the first embodiment of the invention.

In a third embodiment the posture may be evaluated with an intracardiac pressure sensor. The hydrostatic pressure acting on the sensor increases when the patient rises from a prone or supine position to an upright position since the vertical distance upwardly from the sensor within the patient that defines the hydrostatic pressure will increase. The

effects of an increase in pressure on the pressure sensor will generally be similar to the effects of acceleration or gravity on an accelerometer of the type described above. The arrangement described above used for evaluating the accelerometer signal thus could be used also for evaluating the signal from the pressure sensor. Since a pacer system normally contains some kind of activity sensor, the pressure signal also additionally could be evaluated by means of the signal from the activity sensor in order to better distinguish the rise in pressure resulting from a change in posture from a change in pressure resulting from a change in activity.

Figure 8 shows a schematic block diagram of a pacemaker 1 according to the invention including a piezoelectric sensor (pressure sensor) 100', integrator 200, a posture evaluation unit 300', a logic circuit 400, and a pulse generator 500. The logic circuit 400 is also connected to an activity sensor 800. The features in Figure 8 that are identical to features in Figure 1 have the same reference numerals as in Figure 1. The pacemaker 1 is further connected to at least one pacing lead 600 provided with at least one stimulating electrode, this electrode also being used for sensing. The pacemaker 1 further includes processing circuitry for processing the sensing signal(s) from the electrode(s) (not shown). The pacemaker 1 may be arranged for unipolar or bipolar stimulation in a fashion that is well known to those skilled in the art.

The pacemaker 1 shown in Figure 8 thus also comprises a posture evaluation unit 300' for evaluating the integrated signal  $I(t)$  and obtaining a value directly representative of the physical posture of the patient. The digital low pass filtering with a cut-off frequency of 0.5 Hz is performed by the posture evaluation unit 300', or by means not shown connected between the integration unit 200 and the evaluation unit 300'. The posture evaluation unit 300' further compares, at certain predetermined time intervals, the integrated, digitally low pass filtered signal to predefined threshold values. The evaluation unit 300' provides a signal to the logic circuit 400 indicative of different physical posture states, e. g. an increase of about 20 mm Hg would indicate an upright position. Although it may be conceivable to evaluate the physical activity of the patient by means of the short-term characteristics of the pressure signal per se in order to better distinguish the rise in pressure resulting from a change in posture from a change in pressure resulting

from a change in activity, it is preferred that the pressure signal also additionally is evaluated by means of the signal from a separate activity sensor, such as the activity sensor 800. Separate activity sensors are standard features in pacers. It should be noted that in the above embodiment relating to an accelerometer, this accelerometer primarily is an activity sensor and therefore there is no need of a further sensor to check whether a signal indicating a change of posture is a result of a sudden activity or not.

In similarity to the accelerometer-based activity signal used in the two first embodiments described above for determining the posture, the pressure signal also contains components that vary comparatively rapidly with the heart beats. These components would correspond to the constantly present activity and noise contributions superimposed on signal A in Figure 7 and would be superimposed on a pressure signal reflecting the hydrostatic pressure that in turn corresponds to the signal A in Figure 7.

The design of the circuits otherwise is identical to the circuits used above in connection with the above embodiments for an accelerometer.

The intracardiac pressure may, however, also have a component that varies slowly over relatively long time periods, resulting in a very low variation per time unit. These long-term variations also can be detected by means of the above third embodiment of the invention. This is also indicated in Figure 8 with the reference numeral 300'' denoting an analyzer for a long-term trend of change of pressure. This analyzer 300'' is, however, in principle identical to the posture detecting units 300 and 300', the main difference being that the low-pass filter in the trend analysis analyzer 300'' has a cut-off frequency that is considerably lower than the cut-off frequency in the filters in the evaluation unit 300 and 300' and may for instance be 0.05 Hz.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

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MEDICAL IMPLANT

Technical field of the invention

The present invention relates generally to the field of medical implants. More specifically, the present invention relates to an apparatus for providing a signal representing the status of a sensor in a medical implant.

Background of the invention

Ever since the introduction of rate responsive implanted cardiac stimulators, a number of different parameters have been used for determining the activity level of the patient, which in turn is used for controlling the rate at which the heart of a patient is to be stimulated by the pacemaker. One of the most common sensors used is the piezoelectric accelerometer.

Another form of sensor is the intracardiac piezoelectric pressure sensor.

Unlike the piezoresistive and piezocapacitive sensors piezoelectric sensors are not energy consuming, on the contrary they generate their energy themselves. Piezoelectric sensors are also arranged to alter the mechanical stress of the piezoelectric material in response to a change of loads emanating from for instance an acceleration of a seismic mass or from a change in pressure acting on the sensor. This results in a transport of electrons or electrical charges within the material, which provides a change in voltage across the piezoelectric sensor. This voltage corresponds to the load to which the sensor is subjected.

A problem related to measuring the voltage across a piezoelectric sensor is the leakage of charges that

occurs, negatively affecting the accuracy of the measurements. In an attempt to solve this problem, use has been made of a voltage amplifier having very high input impedance. This requires, however, a very large  
5 resistance component, which is undesired within a medical implant. Furthermore, the problem related to leaking charges is still not completely eliminated, and the use of a memory function of some sort would be required. The  
10 problem of leaking charges is of particular interest when the piezoelectric sensor is subjected to relatively small changes in load over long time periods, such as small changes of pressure over a long time or changes in posture.

An object of the present invention is to provide a  
15 method and apparatus for determining the status of a piezoelectric sensor that takes the leakage of charges mentioned above into account.

A further object of the present invention is to  
20 improve the possibilities of evaluating the status of a piezoelectric sensor.

#### Summary of the invention

These objects are achieved in accordance with the present invention having the features found in the main  
25 claim and the preferred embodiments found in the dependent claims.

The invention is based on the insight of at least almost continuously detecting status related sensor output changes and based thereupon generating a signal  
30 representing the actual status of a sensor. Advantageously, said signal is generated by integration of said sensor output changes.

Preferably, use is made of a sensor of the type in which status changes generate changes regarding electri-



cal charges in the sensor. Thus, the sensor is suitably of the piezoelectric type.

In accordance with a preferred aspect of the invention, positive and negative charges generated by the sensor, as more closely discussed below, are substantially continuously detected and removed from the sensor, thereby keeping the output voltage of the sensor at a substantially constant zero level, while at the same time providing an output current which can be the basis for an integration in order to produce said signal.

According to an embodiment of the invention, this can be accomplished by connecting the charge-producing sensor to a circuit having the characteristics of an input impedance that is extremely low or redundant. As a result, charges generated by the piezoelectric sensor will immediately leak to, or be collected or removed by, the connected circuit. This also means that there will be no problem with uncontrolled leakage of charges from the sensor, as is the case in the prior art.

As indicated above, a change of load generates a change of charges in a sensor of the piezoelectric type, all charges generated being collected, i.e. detected and removed from the piezoelectric sensor, by the connected circuit. A change of load can be either positive or negative. A positive change of load will generate an internal transport of charges in a direction opposite that caused by a negative change of load. Furthermore, if a transport of charges in one direction generates a positive voltage across the piezoelectric sensor, a transport of charges in the opposite direction generates a negative voltage. Hence, for restoring a zero voltage level across the sensor from a positive voltage level, there must be a transport of "actual" charges from the sensor, while for restoring a zero level from a negative

voltage, there must be a transport of "actual" charges from the connected circuit to the sensor.

In accordance with the above, the actual charges supplied to the sensor for restoring a zero level will hereinafter be referred to as collected or removed  
5 negative charges, and the resulting current will be referred to as a negative current. Correspondingly, the actual charges removed from the sensor will be referred to as positive charges, and the resulting current as a  
10 positive current. Therefore, both the supply and the removal of charges to and from the sensor will hereinafter be referred to as a collection of charges, wherein a supply of charges to the sensor will be referred to as a collection of negative charges, and a  
15 removal of charges from the sensor will be referred to as a collection of positive charges.

The charges generated in a sensor of the type discussed correspond to the load (e.g. acceleration and/or gravitational force or pressure) to which the  
20 sensor is subjected. Accordingly, each generated charge represents a certain change of load. A greater change of load generates more charges; a more rapid change of load provides a more rapid generation of charges; and an change of load in one direction generates positive  
25 charges and an change of load in the opposite direction generates negative charges (in accordance with the above stated definition of positive and negative charges). Hence, the electric charges generated by the sensor per time unit, i.e. electric current, correspond to the  
30 amount and the direction of the change of load and, hence, to the time derivative of the load to which the sensor is subjected.

The charges generated by a piezoelectric sensor, as described above, are provided to a circuit for detecting

and removing said charges. Since the number of generated charges per time unit, hereinafter referred to as the sensor current or sensor output current, is proportional to the time derivative of the change of load, an  
5 integration of said current will result in an integrated value or signal that is proportional to the load.

The circuit for receiving the current (detecting and removing the charges) is, according to the invention, arranged to integrate said current, i.e. to quantify and  
10 to cumulate the charges generated by the sensor. Accordingly, the resulting value from this integration will represent the net amount, i.e. considering the sign of the generated charges, of charges generated by the sensor. Thus, the integrated value, or signal, will be  
15 directly representative of the load to which the sensor currently is subjected. Said integrated value can therefore be seen as a re-creation of the voltage that would have existed in the sensor, provided that there would have been no leakage or deliberate removal of charges at  
20 all. Thus, the present invention solves the problem regarding obtaining an absolute value representative of the level of for instance a constant acceleration or gravitational force or pressure by the use of a piezoelectric type sensor.

25 As stated above, the restoring in the sensor of a zero level from a negative voltage level would require a supply of charges from the connected circuit to the sensor. According to an embodiment of the invention, the supply of charges can be provided by connecting a  
30 constant direct current, hereinafter referred to as a DC signal, to the sensor and the circuit. If the magnitude of the DC signal exceeds the possible maximum magnitude of the positive and the negative sensor current, the charges or the current supplied to the sensor for

restoring the zero level will be provided by the added DC signal. As a result, the connected circuit will be provided with a combined signal, said combined signal being the sum of the DC signal and the sensor current.

5 The combined signal will, e.g., have the magnitude of the DC signal when the sensor is not affected by a change in acceleration and/or gravitational force or pressure; a magnitude greater than the DC signal when the sensor is affected by a positive change in load, for instance  
10 acceleration and/or gravitational force; and a magnitude less than the DC signal when the sensor is affected by a negative change in said load.

As described above, the connected circuit integrates the sensor current. According to preferred embodiments of  
15 the invention, this integration can be accomplished by first subjecting the sensor current to a current to frequency conversion. The provision of an added DC signal to provide a combined signal, as described above, is particularly advantageous when used in conjunction with a  
20 current to frequency converter, in that the combined signal will always be kept positive and the frequency can be kept proportional to the level of the combined signal.

The current to frequency conversion produces a frequency signal that will be provided to counting means for  
25 counting the pulses comprised in the frequency signal. The counting operation will generate the desired integrated value, after compensation for the contribution from the added DC signal, that will be directly representative of the actual acceleration or gravitational force  
30 by which the sensor is affected.

The contribution of the added DC signal must, however, be eliminated in order to obtain an integrated signal representing the immediate influence of the load on the sensor. According to an embodiment of the

invention, the contribution of the added DC signal can be removed by deducting in the counter a counter value corresponding to the contribution from the DC signal. After each deduction, the counter value, i.e. the integrated value, will represent the contribution from the sensor current only, and, hence, from the load to which the sensor is affected.

The value to be deducted, herein referred to as a deduction value, can be obtained by disconnecting the sensor from the connected circuit for a given time period, and by registering the pulses in the frequency signal during said time period. Disconnection of the sensor can simply be provided by a switch. When said time period expires, the number of pulses registered during this time period is stored as the deduction value and the operation of the connected circuitry continues, using the updated deduction value, as described above. The operation for obtaining the deduction value can be performed at given time intervals, but is preferably performed when there is no sensor current.

According to another advantageous embodiment of the present invention, the problem in compensating for the contribution of the added DC signal can be solved by providing two parallel signal paths, each path being provided with a separate DC signal, as described above, and including current to frequency conversion means; first switching means, for switching the sensor current between the two signal paths; second switching means, for switching the respective frequency signal from the respective signal path between incrementation and decrementation inputs of an up-down counter; and an up-down counter.

The sensor current is periodically switched between the respective paths, so that the sensor current is half

the time provided to the one path, half the time to the other path. As a result, the converted frequency signal output by each path will half the time comprise the converted combined signal, half the time a frequency conversion of the added DC signal. The converted signal, when including the contribution of the DC signal only, can be seen as an idle frequency signal. Obviously, when the sensor current is zero, a frequency conversion of the combined signal will have the same frequency as said idle frequency signal, regardless of the state of the first switching means.

The frequency signal output by each signal path is periodically switched between incrementation and decrementation inputs of an up-down counter. Said switching is preferably performed in conjunction with the switching of the sensor current between the respective signal paths, so that the path presently receiving the sensor current is connected to the incrementation input of the up-down counter, and that the path presently not receiving the sensor current is connected to the decrementation input of the up-down counter. Hence, the respective frequency signal will increment the counter when including the contribution of the sensor current, and decrement the counter when not including the contribution of the sensor current. Accordingly, the contribution of the respective added DC signals will be completely eliminated and the integrated value output by the up-down counter will be directly representative of the current generated by the sensor. The contribution of the respective added DC signal will be completely eliminated, regardless of any drift of the DC signal over time and regardless of the difference between the DC signals.

According to this embodiment, the counter value, i.e. the integrated value, is constantly being updated

and at all times represents the load to which the sensor presently is affected.

One way of determining the activity level of a patient is to use a piezoelectric accelerometer in a  
5 medical implant to determine the physical activity of the patient and consequently the rate at which the heart of the patient is to be stimulated.

However, the heart rate in a healthy individual is also dependent of the individual's static or long term  
10 physical body orientation or posture, or a change from one such orientation to another, e.g. from standing to lying down. The intrinsic heart rate is even dependent of whether the individual is lying in a supine, i.e. on his/her back, or in a prone position, i.e. on his/her  
15 face. Therefore, there is a need for establishing both the activity level and the body posture of a pacemaker patient, in order to control the operation of the pacemaker in dependence of the activity level and the posture of the patient.

20 A number of different methods and devices have been proposed for determining the physical orientation or posture of a patient. Generally, accelerometers are used for determining posture, see for instance EP-0,845,240. This is due to the fact that gravitational force affects  
25 an object in the same manner as would a corresponding constant acceleration force. By determining the effect of gravitation on an accelerometer that is sensitive to acceleration forces in a certain direction only, the gravitation component in this direction can be measured  
30 and, hence, the angle between the axis of sensitivity and the direction of the gravitational force can be determined. Knowing the orientation of the accelerometer relative the patient, the posture of the patient can then easily be established.

The accelerometer can also be combined with one or more accelerometers having different directions of sensitivity, preferably perpendicular to that of the first accelerometer. Thereby, the possibility of detecting different postures of the patient will increase. For instance, the combination with an accelerometer having a sensitivity in the right-left direction of the patient, would enable distinguishing an upright position from a position where the patient is lying on his/her side.

Since the changes in acceleration and gravity connected with changes in posture are relatively slow compared to the changes in acceleration connected with normal physical activity and the device according to the invention takes the leakage of charges from the piezoelectric accelerometer into account, the invention is of particular interest in piezoelectric devices for detecting changes in posture.

As discussed above, the constantly updated integrated value represents the acceleration and/or gravitational force (i.e. the component of the gravitational force in the direction of sensitivity of the accelerometer) to which the accelerometer presently is subjected. The maximum contribution the accelerometer can be subjected to by the gravitational force corresponds to an acceleration of 1 g (9,81 m/s<sup>2</sup>). However, accelerations associated with heavy exercise, such as running, can clearly be in excess of g, sometimes even in excess of 2 g. Therefore, the integrated value will suitably be subjected to further processing in order, e.g., to distinguish between contribution from gravitation and contribution from physical activity.

According to an embodiment of the invention, the constantly updated integrated value can be provided as a digital output signal from the described counting means



to posture evaluation means for determining the posture of the patient. Said posture evaluation means, or means connected between the posture evaluation means and the counting means, performs a digital low pass filtering of the integrated signal. Said low pass filtering, having a preferred cut-off frequency of less than about 1 Hz, preferably about 0,5 Hz, will effectively filter out the contributions of activity, heart beats etc. The low pass filtered integrated signal then can be compared to threshold values for obtaining a posture value indicating the actual posture of the patient. Said posture value can then be provided to control means for controlling the operation of a pacemaker in accordance with the posture of the patient, in a manner known per se.

Likewise, according to a particular embodiment of the invention, the integrated value can also be provided as a digital output signal to activity evaluation means for determining the physical activity of the patient. Said activity evaluation means, or means connected between the activity evaluation means and the counting means, performs a digital band pass filtering of the integrated signal. Said band pass filtering has a preferred lower cut-off frequency of about 1 Hz, and has a preferred upper cut-off frequency of about 10 Hz, preferably about 6 Hz. The band pass filtered integrated signal can then be evaluated in a known manner for obtaining an activity value indicating the physical activity of the patient. Said activity value can then be provided to control means for controlling the operation of a pacemaker in accordance with the physical activity and the posture of the patient.

According to a specific advantageous embodiment of the invention use is made of a piezoelectric accelerometer comprising a two layer beam, one piezoelectric

layer and one supporting layer, said beam being fixed to a mounting surface at one end and provided with a weight at the other end. Thus, when affected by an acceleration or gravitational force change, the beam will deflect about the fixed end. The beam is preferably wide, which would prevent the beam from twisting or deflecting in other directions than intended. The beam can also be tilted. This tilt and the width of the beam will accomplish sensitivity to acceleration and gravitation changes in a direction perpendicular to the mounting surface only. Thus, the piezoelectric accelerometer can be said to be of a monoaxial type. The width of the beam also enhances the magnitude of the current generated by the piezoelectric layer. When the accelerometer is subjected to acceleration and/or gravitational forces directed perpendicular to the mounting surface, the beam will deflect about the fixed end, and the piezoelectric material will generate charges in dependence of the rate and magnitude of the acceleration and/or gravitational changes.

Furthermore, according to this specific embodiment of the invention, the piezoelectric accelerometer is positioned in such a way within a pacemaker that, when the pacemaker is implanted in a patient, the accelerometer beam is positioned vertically with its direction of sensitivity being the anterior-posterior direction of the patient, with the advantages described above. Since the piezoelectric accelerometer is capable of providing negative values, the prone position can easily be distinguished from the supine position.

As indicated above, the invention also is applicable to other piezoelectric sensors, such as endocardial pressure sensors for measuring the intracardiac pressure.

It is for instance possible to determine changes in posture by means of an intracardiac pressure sensor. The hydrostatic pressure acting on the sensor increases when the patient rises from a prone or supine position to an upright position since the vertical distance upwardly from the sensor within the patient that defines the hydrostatic pressure will increase. The effects of an increase in pressure on the pressure sensor will generally be similar to the effects of acceleration or gravity on an accelerometer of the type described above. The arrangement described above used for evaluating the accelerometer signal thus could be used also for evaluating the signal from the pressure sensor. Since a pacer system normally contains some kind of activity sensor, the pressure signal also additionally could be evaluated by means of the signal from the activity sensor in order to better distinguish the rise in pressure resulting from a change in posture from a change in pressure resulting from a change in activity.

A further use of the arrangement according to the invention is to detect long-term changes or drift in the intracardial pressure by means of a pressure sensor.

Further details and aspects of the invention will become apparent from the following detailed description of embodiments of the invention, reference being made to the accompanying drawings.

#### Brief description of the accompanying drawings

Figure 1 illustrates in block diagram form a medical implant comprising an apparatus according to the present invention.

Figure 2 illustrates a piezoelectric accelerometer according to a specific preferred embodiment of the present invention.

Figures 3 and 4 illustrates in a block diagram and in a circuit diagram form an apparatus according to a first embodiment of the invention.

Figures 5 and 6 illustrates in a block diagram and in a circuit diagram form an apparatus according to a second embodiment of the invention.

Figure 7 illustrates in pulse diagram form a method according to the present invention.

Figure 8 illustrates in a block diagram an apparatus according to a third embodiment of the invention.

Detailed description of preferred embodiments of the invention

As mentioned above, the invention is applicable to accelerometers and in particular to accelerometers used in connection with pacemakers and similar for detecting changes in posture, and the invention will be described in more detail below with reference to such an accelerometer. Referring to figure 1 there is shown a schematic block diagram of a pacemaker 1 according to the invention. The pacemaker 1 according to the invention includes a piezoelectric sensor (accelerometer) 100, integrating means 200, posture evaluation means 300, a logic circuit 400, and a pulse generator 500. The logic circuit 400 is also connected to activity evaluation means 700, said means being provided with an activity signal originating from the piezoelectric accelerometer 100. The pacemaker 1 is further connected to at least one pacing lead 600 provided with at least one stimulating electrode, said electrode also being used for sensing. The pacemaker 1 further includes processing circuitry for processing the sensing signal(s) from said electrode(s) (not shown). The pacemaker 1 may be arranged for unipolar

or bipolar stimulation in a fashion that is well known to a person skilled in the art.

The piezoelectric accelerometer 100 will now be described with reference to figure 2. The pacemaker 1 of Fig 1 comprises a piezoelectric monoaxial accelerometer 100, consisting of a two layer beam that is at one end fixed via a support 110 to a surface 120, said beam being tilted with respect to the mounting surface 120. The other end, the open end, is provided with a weight 108 that provides a bending or deflecting motion about the fixed end. The upper layer 102 of the beam is made of a piezoelectric ceramic material, the lower supporting layer 104 consists of a high density, high Young's module material. The support 110, the weight 108 and the supporting layer 104 are all made in one piece, the piece being electrically conductive. The layers are adhesively fixed to each other using an electrically conductive adhesive 106. The free upper side of the piezoelectric layer is coated with a thin metallic layer serving as an electrode. The piezoelectric layer 102 is connected to surrounding circuitry via the conductive layer 104 and a lead 112, connected to the metallic layer.

Referring to figures 3 and 5 there is shown the sensor 100 and the integrating means 200 according to preferred embodiments of the present invention. Said integrating means 200 comprises combining means 201, 202, 203 for combining a sensor output current  $S(t)$  with a DC signal, thereby obtaining a combined signal  $C(t)$  with an offset DC level; converting means 210, 220, 230 for converting the combined signal  $C(t)$  into a frequency signal  $F(t)$ ; and counting means 240, 242 for subjecting said frequency signal  $F(t)$  to a counting operation for obtaining an integrated signal  $I(t)$ .

Referring specifically to figure 3, according to a specific preferred first embodiment of the invention, said integrating means further comprises first switching means  $S_1$ , for repeatedly switching said sensor output  
5 current  $S(t)$  between two parallel signal processing paths, wherein each signal path comprise combining means 201, 202, for combining the sensor output current  $S(t)$  with a respective DC signal  $DC_1$ ,  $DC_2$ , thereby obtaining a respective combined signal  $C_1(t)$ ,  $C_2(t)$ , and converting  
10 means 210, 220, for converting the respective combined signal  $C_1(t)$ ,  $C_2(t)$  to a respective frequency signal  $F_1(t)$ ,  $F_2(t)$ . The integrating means 200 further comprises second switching means  $S_{2,3}$  for switching said frequency signals  $F_1(t)$ ,  $F_2(t)$  between inputs of a counting means  
15 240. Said counting means 240 being provided for combining the output signals  $F_1(t)$ ,  $F_2(t)$  from the two separate signal processing paths, thereby obtaining said integrated signal  $I(t)$ .

The apparatus according to the specific first embodiment of the present invention will now be described  
20 in greater detail with particular reference to the figures 3 and 4. The pacemaker 1 of figure 1 comprises a piezoelectric accelerometer 100, as described above. The integrating means 200 of figure 1 according to this first  
25 embodiment comprises a first switching means  $S_1$  in the form of a switch  $S_1$  for switching the output signal  $S(t)$  from the piezoelectric accelerometer 100 between two parallel, substantially similar signal paths. The switch  $S_1$  is controlled by a constant, periodic control signal  
30 that ensures that the output signal  $S(t)$  from the sensor is provided equal time to the respective signal paths. The switching frequency is typically set from about 100 to about 1000 Hz.

The integrating means 200, in each of the signal paths, also comprises combining means 201, 202, for combining the output current  $S(t)$  from the piezoelectric accelerometer 100 with a DC signal originating from a current source  $DC_1$ ,  $DC_2$ , thereby providing a combined signal  $C_1(t)$ ,  $C_2(t)$ . The magnitude of the added DC signal  $DC_1$ ,  $DC_2$  is greater than the expected maximum value of the accelerometer current from the piezoelectric accelerometer 100.

When the switch  $S_1$  is in a position for switching the sensor output current  $S(t)$  to one signal path, the output from the combination means 201, 202 in the respective other signal path includes only the respective added DC signal.

Furthermore, each signal path of the integrating means 200 comprises converting means 210, 220, in the form of an amplifier circuit functioning as a current to frequency converter, for converting the respective provided combined signal  $C_1(t)$ ,  $C_2(t)$  into a respective frequency signal  $F_1(t)$ ,  $F_2(t)$ . Said respective amplifier circuit comprises a first operational amplifier (op amp) 212, 222; a first and a second capacitor 214, 216, 224, 226, four switches  $S_{11}$ - $S_{14}$ ,  $S_{21}$ - $S_{24}$ ; and a comparator 218, 228. The positions of which can be seen in figure 4. The combined signal  $C_1(t)$ ,  $C_2(t)$ , that is with or without the contribution of the sensor output current  $S(t)$ , is provided to the first operational amplifier 212, 222.

When said switches  $S_{11}$ - $S_{14}$ ,  $S_{21}$ - $S_{24}$  are in the states shown in figure 4, the first operational amplifier 212, 222 is fed back by the first capacitor 214, 224 and charges said capacitor 214, 224. The comparator 218, 228, shown as a second operational amplifier, compares the charge of the first capacitor 214, 224 to a reference voltage  $V_{ref}$ .

When the charge of the first capacitor 214, 224 exceeds the reference voltage, the comparator 218, 228 provides an output signal that produces switching of the switches  $S_{11}$ - $S_{14}$ ,  $S_{21}$ - $S_{24}$  to their second state, thereby  
5 discharging the first capacitor 214, 224 and a charging of the second capacitor 216, 226 commences. When the input signal to the comparator 218, 228 once again exceeds the reference voltage  $V_{ref}$ , the switches  $S_{11}$ - $S_{14}$ ,  $S_{21}$ - $S_{24}$  switch back again and the procedure is repeated. The out-  
10 put signal of the comparator 218, 228 represents the frequency with which the first and second capacitors 214, 216, 224, 226 are discharged. Thus, the output from the comparator 218, 228 provides a respective frequency signal  $F_1(t)$ ,  $F_2(t)$ .

15 The rate by which the capacitors are discharged obviously depends of the current level of the combined input signal  $C_1(t)$ ,  $C_2(t)$ . However, the level of the combined signal  $C_1(t)$ ,  $C_2(t)$  is selected so that the frequency of the output frequency signal  $F_1(t)$ ,  $F_2(t)$ , converted from the combined signal  $C_1(t)$ ,  $C_2(t)$ , always exceeds the switching frequency for switching the switch  $S_1$ . Actually, half the time, the combined signal will be made up solely of the DC signal  $DC_1$ ,  $DC_2$ . When the signal path receives the combined signal  $C_1(t)$ ,  $C_2(t)$  solely con-  
20 taining the DC signal contribution, the output from the comparator constitutes an idle frequency signal  $F_{01}$ ,  $F_{02}$ . The frequency of said idle frequency signal  $F_{01}$ ,  $F_{02}$  will be in the magnitude of 10-100 kHz, i.e. by far exceeding the switching frequency for switching the switch  $S_1$ .

30 The integrating means further comprises second switching means  $S_{2,3}$  in the form of a first switch  $S_2$  and a second switch  $S_3$ , for switching the output frequency signal  $F_1(t)$ ,  $F_2(t)$  from the respective signal path between the respective positive and negative inputs of a



counting means 240. The first and second switch  $S_2$ ,  $S_3$  operate in a reverse manner so that when the first switch  $S_2$  connects one signal path to the positive input of the counting means 240, the second switch  $S_3$  connects the other signal path to the negative input of said counting means 240. The switches  $S_2$ ,  $S_3$  are controlled by the same constant, periodic control signal noted above with respect to controlling the switch of the first switching means  $S_1$ , the switching frequency being 20 Hz. Thus, the respective signal paths are connected to one input of said counting means 240, i.e. the positive input, when the path is currently receiving the sensor output current  $S(t)$ , and, accordingly, is connected to the other input, i.e. the negative input, when the path is not receiving the output signal  $S(t)$  from the piezoelectric accelerometer 100.

The integrating means 200 further comprises a counting means 240 in the form of an up-down counter for counting the pulses of the frequency signal  $F_1(t)$ ,  $F_2(t)$  produced by the above described comparator, thereby obtaining the integrated signal  $I(t)$ . The up-down counter 240 includes a positive input for incrementing the counter 240 and a negative input for decrementing the counter 240. Each output pulse included in the frequency signal  $F_1(t)$ ,  $F_2(t)$  output by the respective comparator 218, 228 produces an incrementation or a decrementation of the counter 240, depending of the state of the switches  $S_2$  and  $S_3$ .

The pacemaker 1 shown in figure 1 further comprises posture evaluation means 300 for evaluating the integrated signal  $I(t)$  and obtaining a value directly representative of the physical posture of the patient. The digital low pass filtering with a cut-off frequency of 0,5 Hz is performed by said posture evaluation means 300,

or by means not shown connected between the integration means 200 and the evaluation means 300. The posture evaluation means further compares, at certain predetermined time intervals, the integrated, digitally low pass  
5 filtered signal to predefined threshold values. The evaluation means 300 provides a signal to the logic circuit 400 indicative of the following physical posture states when the accelerometer is subjected to a gravitational force contribution corresponding to an  
10 acceleration of:

- 1 g, patient lying in a prone position;
- 0 g, patient being in an upright position; and
- 1 g, patient lying in a supine position.

15 The evaluation means 300 can also provide a signal indicative of uncertain posture, e.g. when the posture of the patient changes from a supine to standing position.

According to a specific embodiment of the invention, the pacemaker 1 also comprises activity evaluation means  
20 700 for providing a signal to the logic circuit 400 indicative of the current patient activity. In accordance with the posture evaluation means, the integrated signal  $I(t)$  is subjected to a digital band pass filtering for removing signal contribution that is not related to  
25 patient physical activity. The upper and lower cut-off frequencies of said digital band pass filtering is 1 Hz and 6 Hz, respectively. The digital band pass filtering per se can be performed in a manner well known to the person skilled in the art, and will therefore not be de-  
30 scribed in greater detail. The output signal from said activity evaluation means 700 is then provided to the logic circuit 400.

The pacemaker 1 shown in figure 1 further comprises a logic circuit 400 and a pulse generator 500 for con-

trolling, regulating and delivering pacing pulses, via the pacing leads, to the atrium and/or ventricle of the heart. Said controlling is performed at least on the basis of the posture and activity of the patient in a manner known to the person skilled in the art. It should be understood that means and circuits required for the conventional operation of a pacemaker according to the state of the art is included in the pacemaker according to the present invention, although not shown or described herein.

With particular reference now to figure 7, there is shown in diagrammatic form how an acceleration contribution, in an idealised form for explanatory reasons, is represented by the integrated signal. The pulse diagram consists of six different signals (A-F) divided into five time periods by the dotted lines (1-5).

A is the idealised contribution of the gravitation component, in the sensitivity direction of the accelerometer, to which the accelerometer is affected. In a true case, this would be superimposed by the activity and noise contributions constantly present.

B is the current generated by a piezoelectric accelerometer that is subjected to the gravitation component according to A, i.e. the sensor output current  $S(t)$ . This current is proportional to the derivative of the acceleration.

C is the control signal controlling the switches  $S_1$ - $S_3$ , i.e. the switching of the sensor output current  $S(t)$  between the parallel signal paths and the switching to the up-down counter.

D are the output signal pulses delivered by the comparator 218 of the upper signal path, and E are the pulses delivered by the comparator 228 of the lower signal path, in the manner described above. Said respective

pulses control the respective switches  $S_{11}$ - $S_{24}$  and triggers the incrementation and decrementation of the up-down counter 240. The difference in pulse width is only to illustrate the fact that a difference in the magnitude of the respective DC signals  $DC_1$ ,  $DC_2$  does not effect the performance of the integrating means. The contributions of the DC signals  $DC_1$ ,  $DC_2$  are completely eliminated.

F is the resulting integrated signal  $I(t)$  registered in the counter 240 and provided to the posture evaluation means 300.

During the time intervals 1-2, 3-4 and 5-6, the sensor output current  $S(t)$  is switched to the upper signal path, the comparator of which is switched to the positive input of the up-down counter 240. Accordingly, during these time intervals, signal D increments and signal E decrements the up-down counter 240. Consequently, during time periods 2-3 and 4-5, the sensor output current is switched to the lower signal path L, signal E increments the counter and signal D decrements the counter.

As can be seen in figure 7, the level of the integrated signal  $I(t)$  provided by the counter 240 closely match the gravitation component to which the piezoelectric accelerometer 100 currently is subjected. Hence, the output of the integrating means according to the invention provides a direct absolute value representing the current deflection of the accelerometer beam and, hence, the current gravitation (or acceleration).

Now, with particular reference to figures 5 and 6, an apparatus according to an alternative second embodiment of the invention will be described. According to this alternative second embodiment, the integrating means 200 shown in figure 1 comprises only one signal path, thereby precluding the need for first and second switching means for switching the sensor output current  $S(t)$

between separate signal paths. As noted above, the integrating means 200 comprises combining means 203, converting means 230, and counting means 242. The converting means 230 are in the form of an amplifier circuit, said  
5 amplifier circuit comprises a first operational amplifier 232; a first and a second capacitor 234, 236, four switches  $S_{31}$ - $S_{34}$ ; and a comparator 238. The functions of the combining means 203, the converting means 230, and the components comprised in the converting means 230, are  
10 similar to the functions of the corresponding means and components described above with particular reference to the figures 3 and 4, and will therefore not be described in greater detail.

The counting means 242, according to this second  
15 embodiment, further comprises a counter for counting the pulses of the frequency signal  $F(t)$ , produced by the comparator 238. As described above, the DC signal is superimposed on the sensor output current  $S(t)$ . The contribution from the DC signal is removed by deducting, at  
20 predefined time intervals, e.g. every 1-10 ms, a counter value corresponding to the contribution from the DC signal. The integrated signal  $I(t)$  output from the counter is updated after each deduction, and the integrated signal  $I(t)$  is representative of the acceleration or gravi-  
25 tation.

The counter value to be deducted, a deduction value, is obtained by disconnecting, at certain given time intervals, e.g. 1 hour, for a given time period, e.g. 1  
30 sec, the piezoelectric accelerometer 100 from the combining means 203 by the opening of a switch (not shown) positioned between the accelerometer 100 and the combining means 203. When the time period expires, the number of pulses registered during this time period is stored as the new deduction value, the switch is closed, and the

operation of the integrating means 200 continues, with the updated deduction value, as described above.

The pacemaker 1, according to this second embodiment of the invention, also comprises posture evaluation means 5 300, a logic circuit 400, a pulse generator 500, and activity evaluation means 700, in the same manner and with the same functions as described above with reference to the first embodiment of the invention.

In a third embodiment the posture may be evaluated 10 with an intracardiac pressure sensor. The hydrostatic pressure acting on the sensor increases when the patient rises from a prone or supine position to an upright position since the vertical distance upwardly from the sensor within the patient that defines the hydrostatic 15 pressure will increase. The effects of an increase in pressure on the pressure sensor will generally be similar to the effects of acceleration or gravity on an accelerometer of the type described above. The arrangement described above used for evaluating the 20 accelerometer signal thus could be used also for evaluating the signal from the pressure sensor. Since a pacer system normally contains some kind of activity sensor, the pressure signal also additionally could be 25 evaluated by means of the signal from the activity sensor in order to better distinguish the rise in pressure resulting from a change in posture from a change in pressure resulting from a change in activity.

Referring to figure 8 there is shown a schematic block diagram of a pacemaker 1 according to the invention 30 including a piezoelectric sensor (pressure sensor) 100', integrating means 200, posture evaluation means 300', a logic circuit 400, and a pulse generator 500. The logic circuit 400 is also connected to an activity sensor 800. The features in this drawing that are identical to

features in Fig 1 have the same reference numerals as in Fig 1. The pacemaker 1 is further connected to at least one pacing lead 600 provided with at least one stimulating electrode, said electrode also being used for sensing. The pacemaker 1 further includes processing circuitry for processing the sensing signal(s) from said electrode(s) (not shown). The pacemaker 1 may be arranged for unipolar or bipolar stimulation in a fashion that is well known to a person skilled in the art.

10 The pacemaker 1 shown in figure 8 thus also comprises posture evaluation means 300' for evaluating the integrated signal  $I(t)$  and obtaining a value directly representative of the physical posture of the patient. The digital low pass filtering with a cut-off frequency of 0,5 Hz is performed by said posture evaluation means 15 300', or by means not shown connected between the integration means 200 and the evaluation means 300'. The posture evaluation means further compares, at certain predetermined time intervals, the integrated, digitally low pass filtered signal to predefined threshold values. The 20 evaluation means 300' provides a signal to the logic circuit 400 indicative of different physical posture states, e. g. an increase of about 20 mm Hg would indicate an upright position. Although it may be conceivable to 25 evaluate the physical activity of the patient by means of the short-term characteristics of the pressure signal per se in order to better distinguish the rise in pressure resulting from a change in posture from a change in pressure resulting from a change in activity, it is 30 preferred that the pressure signal also additionally is evaluated by means of the signal from a separate activity sensor, such as activity sensor 800. Separate activity sensors are standard features in pacers. It should be noted that in the above embodiment relating to an

accelerometer, this accelerometer primarily is an activity sensor and therefore there is no further need of a further sensor to check whether a signal indicating a change of posture is a result of a sudden activity or not.

In similarity to the accelerometer-based activity signal used in the two first embodiments described above for determining the posture, the pressure signal also contains components that varies comparatively rapidly with the heart beats. These components would correspond to the constantly present activity and noise contributions superimposed on signal A in Fig 7 and would be superimposed on a pressure signal reflecting the hydrostatic pressure that in turn corresponds to the signal A in Fig 7.

The design of the circuits otherwise is identical to the circuits used above in connection with the above embodiments for an accelerometer.

The intracardiac pressure may however also comprise a component that varies slowly over relatively long time periods of time, resulting in a very low variation per time unit. These long-term variations can also be detected by means of the above third embodiment of the invention. This is also indicated in Fig 8 with the reference numeral 300" denoting a long-term trend of change of pressure analysis means. This means is however in principle identical to the posture detecting means 300 and 300', the main difference being that the low-pass filter in the trend analysis means has a cut-off frequency that is considerably lower than the cut-off frequency in the filters in the evaluation means 300 and 300' and may for instance be 0.05 Hz.



## CLAIMS

1. An apparatus for providing a signal representing the status of a sensor (100,100') in a medical implant (1), preferably a heart stimulator, comprising:

5 a sensor (100,100') which generates positive and negative charges in response to positive and negative changes in loads, e.g. acceleration and/or gravitational forces or pressure, by which the sensor (100,100') is affected;

10 means for detecting and removing substantially all generated positive and negative charges from the sensor (100,100'), thereby keeping the accumulated charge potential of the sensor (100,100') at a substantially zero level, said detected positive and negative charges  
15 constituting a sensor output current (S(t));

means for integrating the sensor output current (S(t)), thereby providing an integrated signal (I(t)), said signal representing the status of the sensor (100,100'), wherein said integrating means comprises:

20 current-to-frequency converting means for converting the sensor output current (S(t)) into a frequency signal (F(t)) having a frequency representing a level of said sensor output current (S(t)); and

25 counting means for subjecting said frequency signal (F(t)) from the converting means to a counting operation for obtaining said integrated signal (I(t)).

2. The apparatus according to claim 1, wherein said sensor (100,100') is of the piezoelectric type.

3. The apparatus according to any one of the preceding claims, wherein said integrating means further comprises:

means for combining said sensor output current  
5 (S(t)) with a DC signal (DC), thereby obtaining a combined signal (C(t)) having an offset DC level, said DC signal (DC) being such that a change of sign of the sensor output current (S(t)) does not result in any change  
10 of sign of the combined signal (C(t)), and wherein said integrating means is adapted to integrate the combined signal (C(t)) for obtaining said integrated signal; and  
means for removing an integration contribution of said DC signal (DC).

15 4. The apparatus according to claim 3, wherein said means for removing the integration contribution of the DC signal (DC) comprises:

first switching means (S<sub>1</sub>) for repeatedly switching  
said sensor output current (S(t)) between two parallel  
20 signal processing paths;

means for generating an output signal, wherein said  
means for generating an output signal is adapted to generate, as said output signal, an information output signal  
25 based on the combined signal when the path is receiving the sensor output current (S(t)) and to generate, as said output signal, an idle output signal based on the DC signal when the path is not receiving the sensor output current; and

means for combining the output signals from the two  
30 signal processing paths.

5. The apparatus according to claim 4, wherein each signal processing path of said two signal processing paths further comprises:

means for combining said sensor output current ( $S(t)$ ), when it has been received in the signal processing path, with a DC signal ( $DC_1$ ,  $DC_2$ ) thereby obtaining in said path a combined signal ( $C_1(t)$ ,  $C_2(t)$ ) having an offset DC level; and

means for converting said combined signal ( $C_1(t)$ ,  $C_2(t)$ ) to a frequency signal ( $F_1(t)$ ,  $F_2(t)$ ) having a frequency corresponding to a level of said combined signal ( $C_1(t)$ ,  $C_2(t)$ ) such that said output signal presents a non-zero frequency and

wherein said means for combining the output signals from the two signal processing paths is a counting means.

6. The apparatus according to claim 3, wherein said integrating means further comprises:

means for alternately charging, by said combined signal ( $C(t)$ ), and discharging a first and a second capacitance means (234, 236) in such a manner that when one is being charged by said combined signal ( $C(t)$ ), the other is being discharged, and such that a completed charging of the first capacitance means (234) initiates a discharging of the first capacitance means (234) and a charging of the second capacitance means (236), and vice versa, and wherein each discharging generates a corresponding discharge pulse; and

counting means (242) for counting said discharge pulses and thereby generating a count value corresponding to an integrated signal ( $I(t)$ ) of said combined signal.

7. The apparatus according to claim 6, wherein said counting means (242) further comprises means for removing an integration contribution of said DC signal ( $DC$ ) by deducting from said count value a deduction value corresponding to said integration contribution, thereby gene-

rating a reduced count value forming said integrated signal (I(t)).

8. The apparatus according to any one of the  
5 preceding claims, further comprising evaluating means (300,300',300") for evaluating the integrated signal (I(t)), thereby obtaining information related to the status of the sensor (100,100'), wherein said evaluating means comprises filtering means for filtering out unde-  
10 sired information from the integrated signal (I(t)).

9. The apparatus according to claim 8, wherein said filtering means are adapted to low pass filter the integrated signal (I(t)), and wherein said evaluating means  
15 (300,300',300") are adapted to evaluate said low pass filtered signal, thereby obtaining a value representing an orientation of the medical implant (1) or the patient.

10. The apparatus according to claim 9, wherein said  
20 evaluating means (300,300',300") also comprises means for comparing said low pass filtered signal with predefined threshold values, each of which corresponds to a specific predefined orientation of the medical implant (1), thereby obtaining a value representing the orientation of  
25 the medical implant (1) or the patient.

11. The apparatus according to any one of claims 8-  
10, comprising additional evaluating means (700), said  
additional evaluating means (700) comprising band pass  
30 filtering means for band pass filtering of the integrated signal (I(t)), and wherein said additional evaluating means (700) are adapted to evaluate said band pass filtered signal, thereby obtaining a value representing a

physical activity level of a carrier of said medical implant (1).

5 12. The apparatus according to any one of the preceding claims, wherein said sensor (100) is sensitive for positive and negative changes in acceleration and/or gravitational forces in one direction or axis only.

10 13. The apparatus according to anyone of claims 2 - 10, wherein said apparatus is connected to activity sensing means (800) for determining whether a change in load on said piezoelectric sensor (100') is a result of physical activity of the patient or not.

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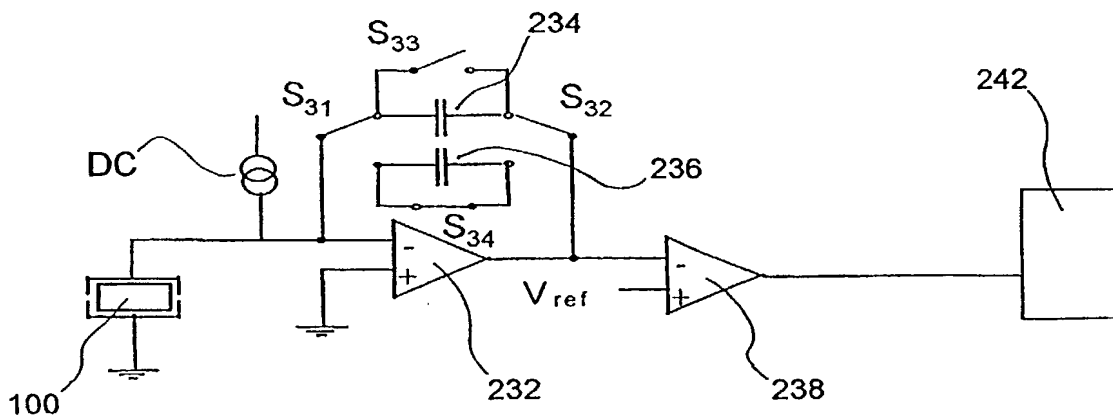
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(54) Title: MEDICAL IMPLANT



(57) Abstract

The invention relates to an apparatus for determining the actual status of a piezoelectric sensor in a medical implant. Electrical charges generated in the sensor, in response to changes in acceleration and/or gravitational forces or other loads by which the sensor is affected, are continuously detected and removed from the sensor, thereby keeping the voltage across the sensor at a substantially constant zero level. The detected charges, both positive and negative in accordance with the corresponding changes in acceleration and/or gravitational forces or other loads, are integrated, thereby providing a resulting integrated signal representing the actual status of the sensor. The integrated signal is then evaluated for determining, e.g., the physical activity and/or the posture of a patient carrying the medical implant.

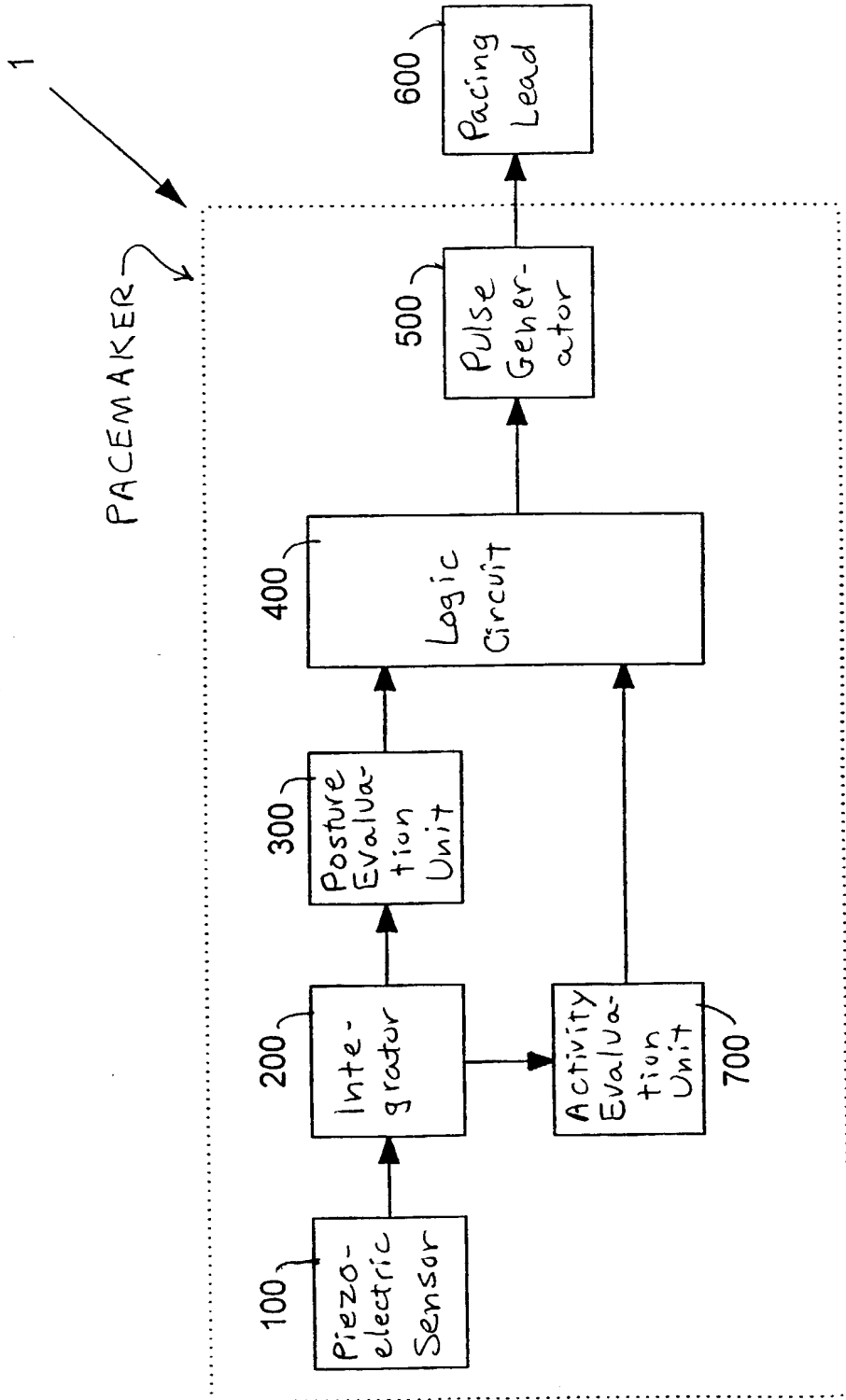


Figure 1

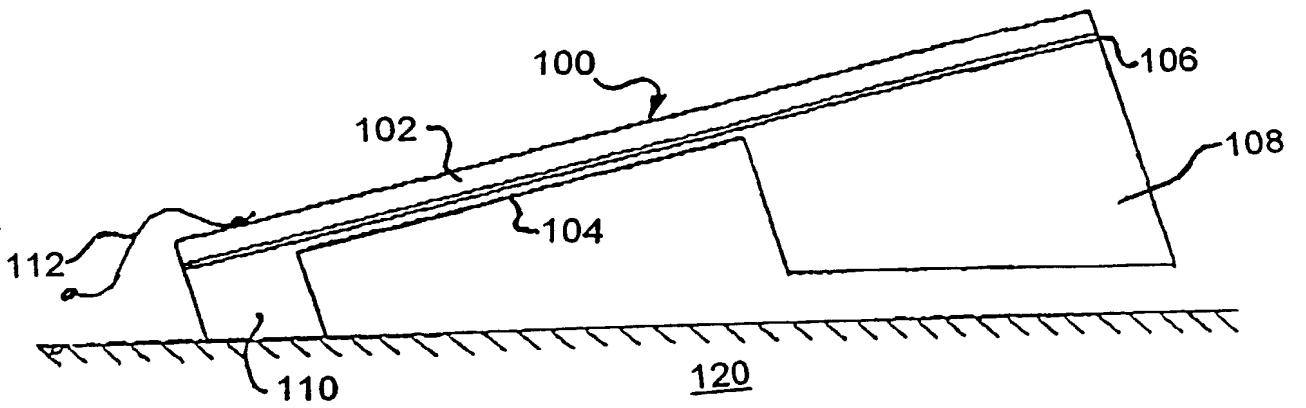


Fig. 2



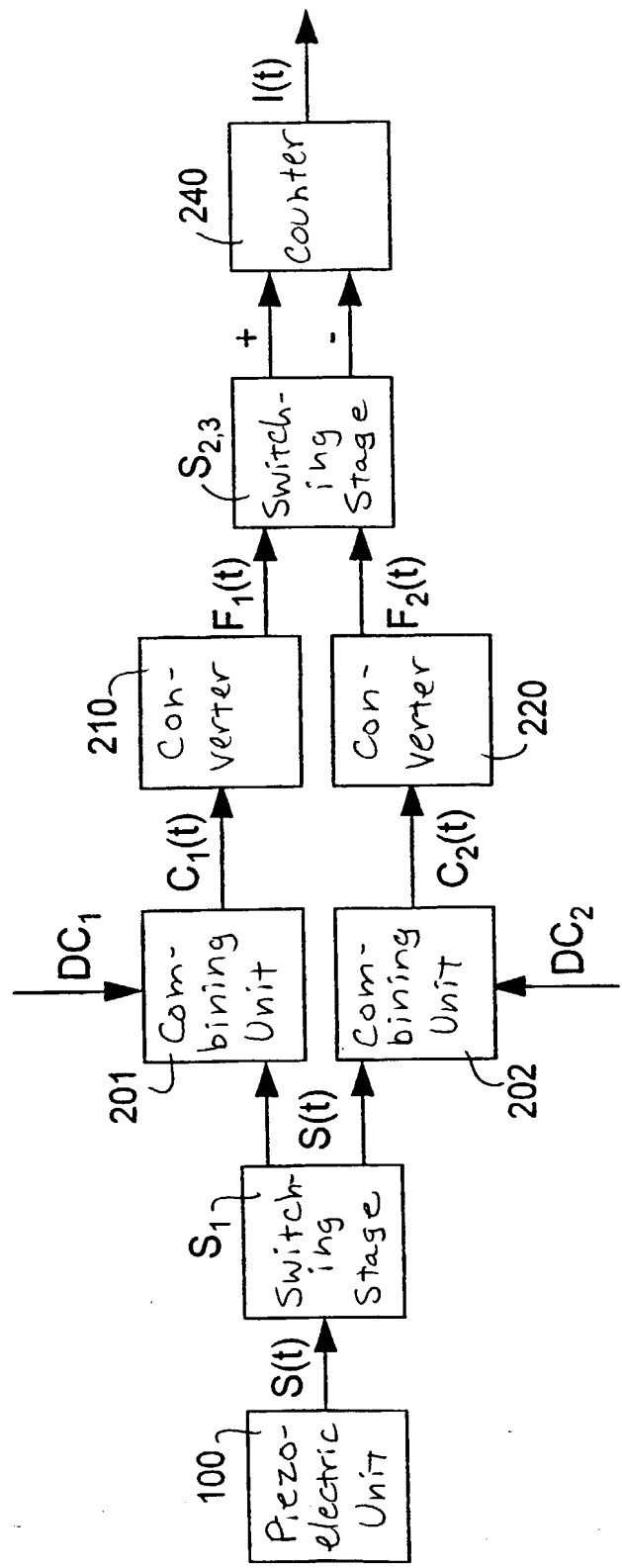


Fig. 3

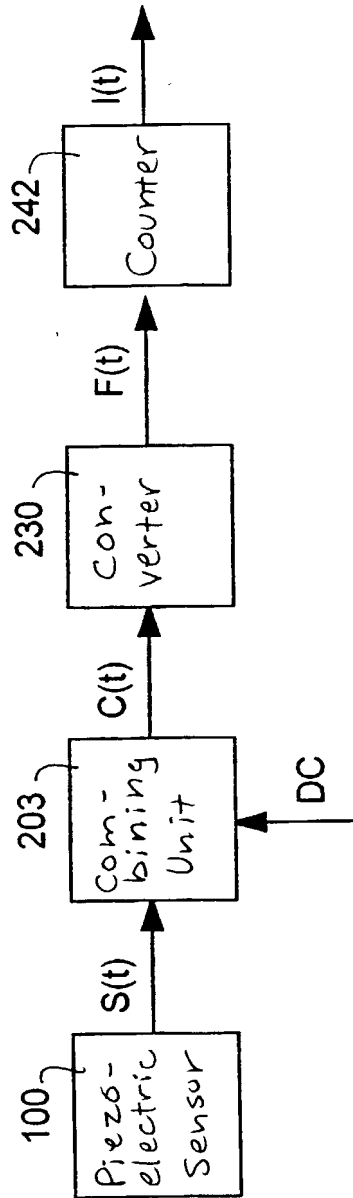


Fig. 5

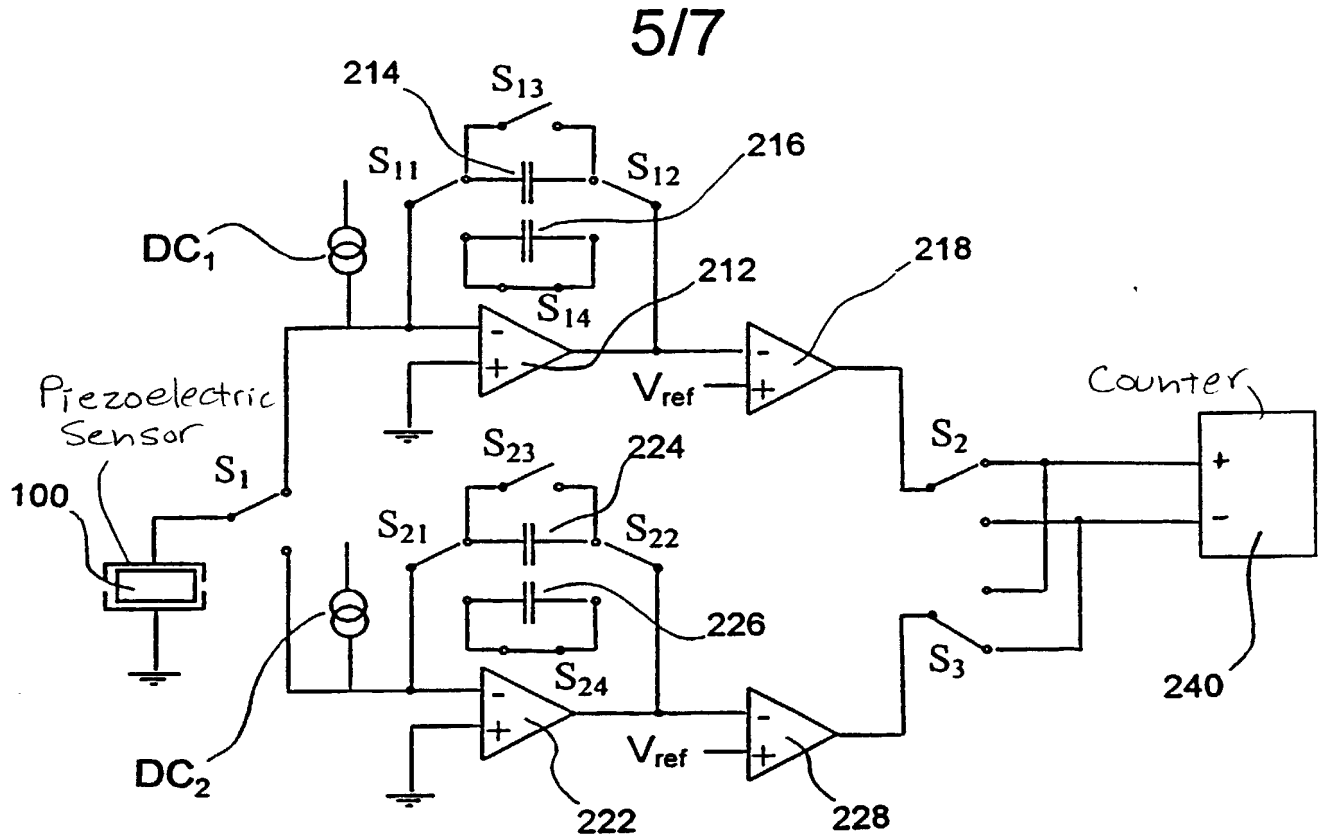


Fig. 4

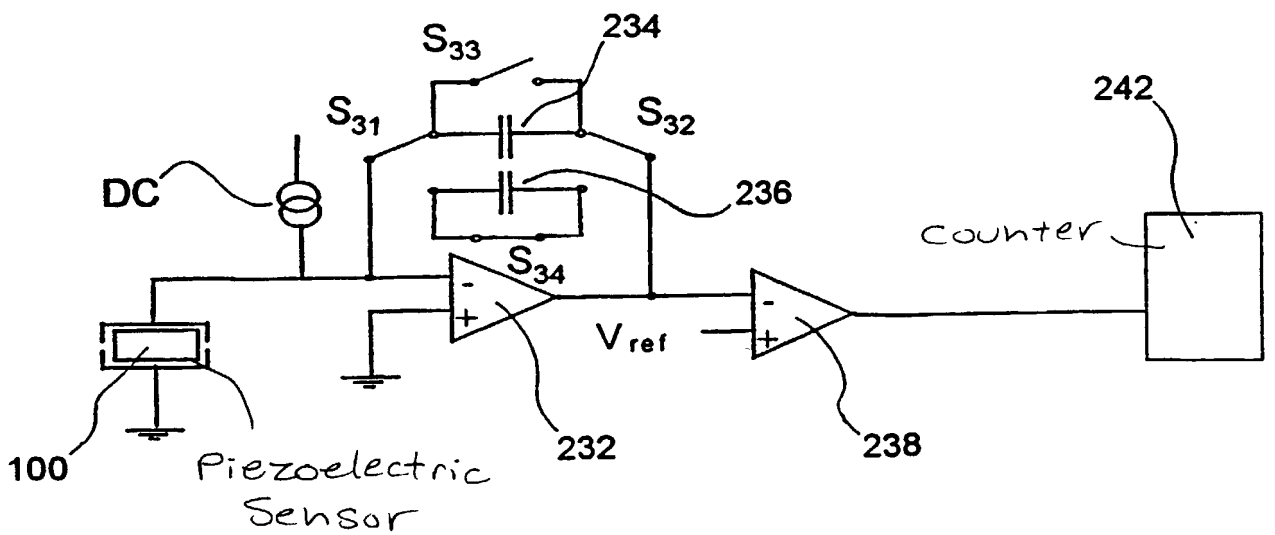


Fig. 6

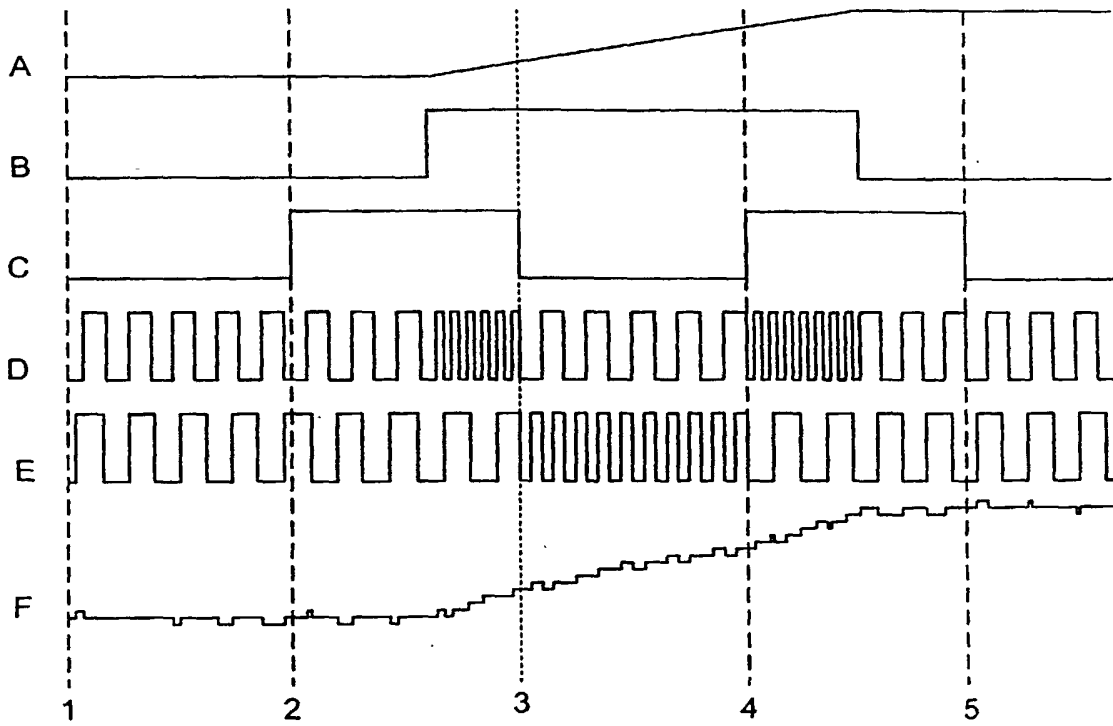


Fig. 7

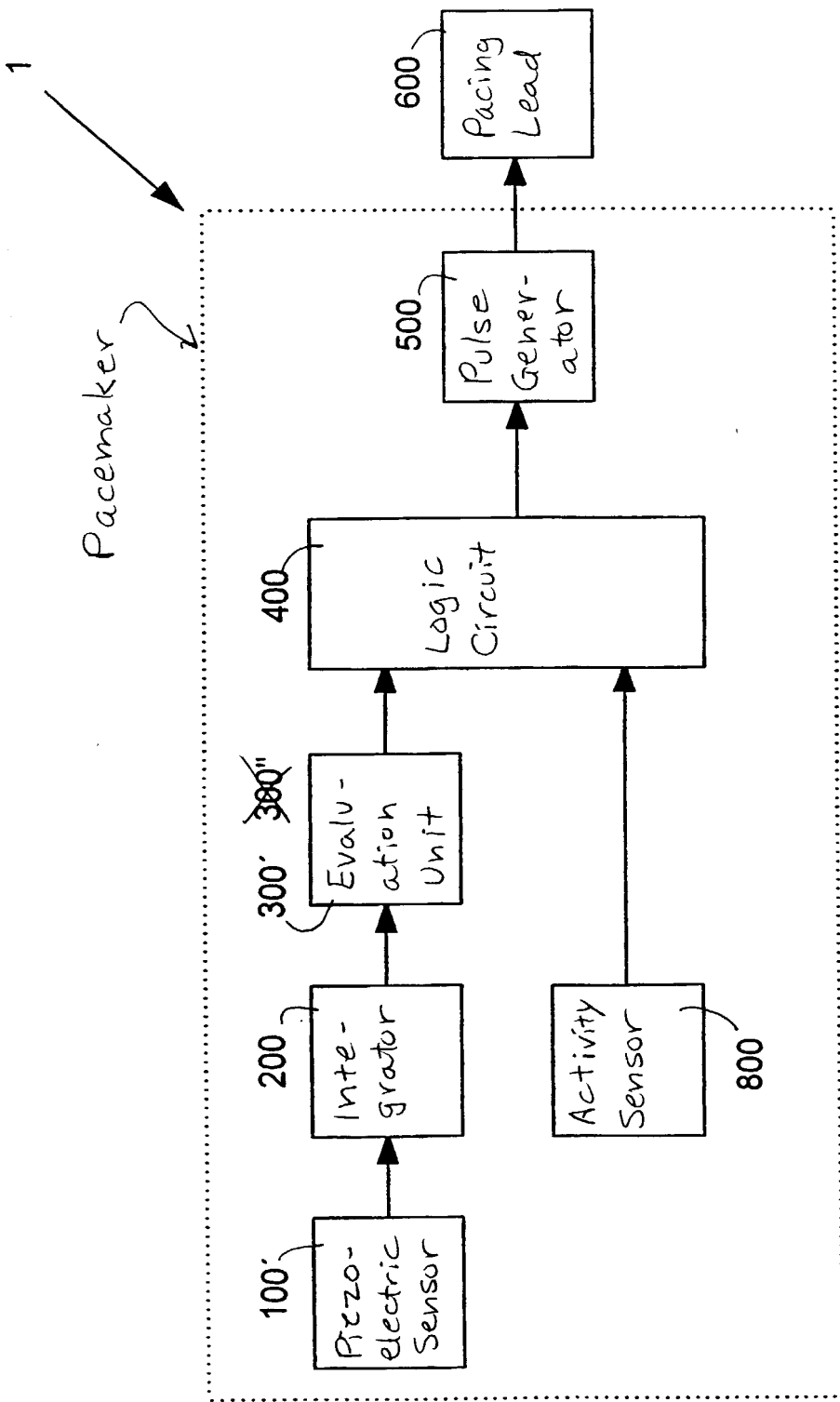


Fig. 8



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SIGNATURE OF INVENTOR 201 <i>Johan Lidman</i>	SIGNATURE OF INVENTOR 202 <i>Lars Landelius</i>	SIGNATURE OF INVENTOR 203 <i>Charlotte Kjellman</i>
DATE <u>September 19, 2001</u>	DATE <u>September 24, 2001</u>	DATE <u>September 12, 2001</u>